



Rural Health Clinic Version

Module 6

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TITLE 42 - PUBLIC HEALTH

Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter G - Standards and Certification

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PART 491 - CERTIFICATION OF CERTAIN HEALTH FACILITIES

Authority: 42 U.S.C. 263a and 1302.

Subpart A - Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act).

[57 FR 24982, June 12, 1992]

§ 491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by the clinic's staff.

FQHC means an entity as defined in § 405.2401(b).

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

- (1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or
- (2) Has satisfactorily completed a formal 1 academic year educational program that:
 - (i) Prepares registered nurses to perform an expanded role in the delivery of primary care;
 - (ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and
 - (iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or
- (3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician means the following:

- (1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and
- (2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations).

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

- (1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or
- (2) Has satisfactorily completed a program for preparing physician's assistants that:
 - (i) Was at least 1 academic year in length;
 - (ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and
 - (iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or
- (3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

[71 FR 55345, Sept. 22, 2006, as amended at 79 FR 27156, May 12, 2014]

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

[71 FR 55346, Sept. 22, 2006]

§ 491.4 Compliance with Federal, State and local laws.

The rural health clinic or FQHC and its staff are in compliance with applicable Federal, State and local laws and regulations.

- (a) *Licensure of clinic or center.* The clinic or center is licensed pursuant to applicable State and local law.
- (b) *Licensure, certification or registration of personnel.* Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

[57 FR 24982, June 12, 1992]

§ 491.5 Location of clinic.

- (a) *Basic requirements.*
 - (1) An RHC is located in a rural area that is designated as a shortage area.
 - (2) An FQHC is located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population.
 - (3) Both the RHC and the FQHC may be permanent or mobile units.
 - (i) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.
 - (ii) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a mobile structure, which has fixed, scheduled location(s).

- (iii) **Permanent unit in more than one location.** If clinic or center services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic or for approval as an FQHC.

(b) **Exceptions.**

- (1) CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.
- (2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.
- (3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

(c) **Criteria for designation of rural areas.**

- (1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.
- (2) Excluded from the rural area classification are:
 - (i) Central cities of 50,000 inhabitants or more;
 - (ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;
 - (iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.
- (3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

(d) **Criteria for designation of shortage areas.**

- (1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:
 - (i) The ratio of primary care physicians practicing within the area to the resident population;
 - (ii) The infant mortality rate;
 - (iii) The percent of the population 65 years of age or older; and
 - (iv) The percent of the population with a family income below the poverty level.
- (2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:
 - (i) The area served is a rational area for the delivery of primary medical care services;
 - (ii) The ratio of primary care physicians practicing within the area to the resident population; and
 - (iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

(e) **Medically underserved population.** A medically underserved population includes the following:

- (1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.
- (2) A population group that is designated by PHS as having a shortage of personal health services.

(f) **Requirements specific to FQHCs.** An FQHC approved for participation in Medicare must meet one of the following criteria:

- (1) Furnish services to a medically underserved population.
- (2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

Cross Reference:

See 42 CFR 110.203(g) (41 FR 45718, Oct. 15, 1976) and 42 CFR Part 5 (42 FR 1586, Jan. 10, 1978).

[43 FR 5375, Feb. 8, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, and amended at 57 FR 24982, June 12, 1992; 61 FR 14658, Apr. 3, 1996; 68 FR 74816, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006]

§ 491.6 Physical plant and environment.

- (a) **Construction.** The clinic or center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.
- (b) **Maintenance.** The clinic or center has a preventive maintenance program to ensure that:
 - (1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;
 - (2) Drugs and biologicals are appropriately stored; and
 - (3) The premises are clean and orderly.

§ 491.7 Organizational structure.**(a) Basic requirements.**

- (1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.
- (2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

(b) Disclosure. The clinic or center discloses the names and addresses of:

- (1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);
- (2) The person principally responsible for directing the operation of the clinic or center; and
- (3) The person responsible for medical direction.

[57 FR 24983, June 12, 1992]

§ 491.8 Staffing and staff responsibilities.**(a) Staffing.**

- (1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.
- (2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.
- (3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.
- (4) The staff may also include ancillary personnel who are supervised by the professional staff.
- (5) The staff is sufficient to provide the services essential to the operation of the clinic or center.
- (6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

(b) Physician responsibilities. The physician performs the following:

- (1) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.
- (2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients.
- (3) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

(c) Physician assistant and nurse practitioner responsibilities.

- (1) The physician assistant and the nurse practitioner members of the clinic's or center's staff:
 - (i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;
 - (ii) Participate with a physician in a periodic review of the patients' health records.
- (2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:
 - (i) Provides services in accordance with the clinic's or center's policies;
 - (ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and
 - (iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

(d) COVID-19 vaccination of staff. The RHC/FQHC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

- (1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following clinic or center staff, who provide any care, treatment, or other services for the clinic or center and/or its patients:
 - (i) RHC/FQHC employees;
 - (ii) Licensed practitioners;
 - (iii) Students, trainees, and volunteers; and
 - (iv) Individuals who provide care, treatment, or other services for the clinic or center and/or its patients, under contract or by other arrangement.
- (2) The policies and procedures of this section do not apply to the following clinic or center staff:
 - (i) Staff who exclusively provide telehealth or telemedicine services outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section; and
 - (ii) Staff who provide support services for the clinic or center that are performed exclusively outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section.
- (3) The policies and procedures must include, at a minimum, the following components:
 - (i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the clinic or center and/or its patients;
 - (ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;
 - (iii) A process for ensuring that the clinic or center follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;
 - (iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (d)(1) of this section;
 - (v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;
 - (vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - (vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;
 - (viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:
 - (A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and
 - (B) A statement by the authenticating practitioner recommending that the staff member be exempted from the clinic's or center's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - (ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
 - (x) Contingency plans for staff who are not fully vaccinated for COVID-19.

[57 FR 24983, June 12, 1992, as amended at 61 FR 14658, Apr. 3, 1996; 68 FR 74817, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006; 79 FR 25480, May 2, 2014; 79 FR 27156, May 12, 2014; 86 FR 61626, Nov. 5, 2021]

§ 491.9 Provision of services.

- (a) **Basic requirements.**
 - (1) All services offered by the clinic or center are furnished in accordance with applicable Federal, State, and local laws; and
 - (2) The clinic or center is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, but do not apply to FQHCs.

(b) **Patient care policies.**

- (1) The clinic's or center's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.
- (2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic or center staff.
- (3) The policies include:
 - (i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.
 - (ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.
 - (iii) Rules for the storage, handling, and administration of drugs and biologicals.
- (4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the RHC or FQHC.

(c) **Direct services -**

- (1) **General.** The clinic or center staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.
- (2) **Laboratory.** These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:
 - (i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);
 - (ii) Hemoglobin or hematocrit;
 - (iii) Blood glucose;
 - (iv) Examination of stool specimens for occult blood;
 - (v) Pregnancy tests; and
 - (vi) Primary culturing for transmittal to a certified laboratory.
- (3) **Emergency.** The clinic or center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) **Services provided through agreements or arrangements.**

- (1) The clinic or center has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:
 - (i) Inpatient hospital care;
 - (ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and
 - (iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.
- (2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

[57 FR 24983, June 12, 1992, as amended at 58 FR 63536, Dec. 2, 1993; 84 FR 51832, Sept. 30, 2019]

§ 491.10 Patient health records.

(a) **Records system.**

- (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.
- (2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.
- (3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:
 - (i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

- (ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;
- (iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;
- (iv) Signatures of the physician or other health care professional.

(b) **Protection of record information.**

- (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.
- (2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.
- (3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) **Retention of records.** The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

§ 491.11 Program evaluation.

- (a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program.
- (b) The evaluation includes review of:
 - (1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;
 - (2) A representative sample of both active and closed clinical records; and
 - (3) The clinic's or center's health care policies.
- (c) The purpose of the evaluation is to determine whether:
 - (1) The utilization of services was appropriate;
 - (2) The established policies were followed; and
 - (3) Any changes are needed.
- (d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[71 FR 55346, Sept. 22, 2006, as amended at 84 FR 51832, Sept. 30, 2019]

§ 491.12 Emergency preparedness.

The Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) must comply with all applicable Federal, State, and local emergency preparedness requirements. The RHC/FQHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

- (a) **Emergency plan.** The RHC or FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:
 - (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
 - (2) Include strategies for addressing emergency events identified by the risk assessment.
 - (3) Address patient population, including, but not limited to, the type of services the RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
 - (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.
- (b) **Policies and procedures.** The RHC or FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:
 - (1) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.
 - (2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.
 - (3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.



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Title 42 - Public Health

Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter B - Medicare Program

Part 413

- Principles of Reasonable Cost Reimbursement; Payment for End-Stage Renal Disease Services; Prospectively Determined Payment Rates for Skilled Nursing Facilities; Payment for Acute Kidney Injury Dialysis

Subpart E - Payments to Providers

EDITORIAL NOTE ON PART 413

Editorial Note: Nomenclature changes to part 413 appear at 76 FR 50537, August 22, 2014.

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) *Scope and definitions.*

(1) *Scope.*

- (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.
- (ii) The determinations of provider-based status for payment purposes described in this section are not made as to whether the following facilities are provider-based:
 - (A) Ambulatory surgical centers (ASCs).
 - (B) Comprehensive outpatient rehabilitation facilities (CORFs).
 - (C) Home health agencies (HHAs).
 - (D) Skilled nursing facilities (SNFs) (determinations for SNFs are made in accordance with the criteria set forth in § 483.5 of this chapter).
 - (E) Hospices.
 - (F) Inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services.
 - (G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, other than those clinical diagnostic laboratories operating as parts of CAHs on or after October 1, 2010, or facilities that furnish only some combination of these services.
 - (H) Facilities, other than those operating as parts of CAHs, furnishing only physical, occupational, or speech therapy to ambulatory patients, throughout any period during which the annual financial cap amount on payment for coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, is suspended by legislation.
 - (I) ESRD facilities (determinations for ESRD facilities are made under § 413.174 of this chapter).
 - (J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).
 - (K) Ambulances.
 - (L) Rural health clinics (RHCs) affiliated with hospitals having 50 or more beds.

(2) **Definitions.** In this subpart E, unless the context indicates otherwise -

Campus means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term "department of a provider" does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

Free-standing facility means an entity that furnishes health care services to Medicare beneficiaries and that is not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity.

Main provider means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Provider-based status means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term "remote location of a hospital" does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.

(b) **Provider-based determinations.**

- (1) A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based.
- (2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of this section will not apply to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.
- (3)
 - (i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient

departments and hospital-based entities described in paragraph (g) of this section. The provider seeking such a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and to CMS contractors upon request. If the facility is operated as a joint venture, the provider would also have to attest that it will comply with the requirements of paragraph (f) of this section.

- (ii) If the facility is not located on the campus of the potential main provider, the provider seeking a determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.
 - (iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.
 - (iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.
- (4) A facility that is not located on the campus of a hospital and that is used as a site where physician services of the kind ordinarily furnished in physician offices are furnished is presumed as a free-standing facility, unless CMS determines the facility has provider-based status.
 - (5) A facility that has requested provider-based status in relation to a hospital or CAH on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS determines that the facility does not qualify for provider-based status.
- (c) **Reporting of material changes in relationships.** A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.
 - (d) **Requirements applicable to all facilities or organizations.** Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:
 - (1) **Licensure.** The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.
 - (2) **Clinical services.** The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:
 - (i) Professional staff of the facility or organization have clinical privileges at the main provider.
 - (ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.
 - (iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a

department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

- (iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.
 - (v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.
 - (vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.
- (3) **Financial integration.** The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.
- (4) **Public awareness.** The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.
- (5) **Obligations of hospital outpatient departments and hospital-based entities.** In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.
- (e) **Additional requirements applicable to off-campus facilities or organizations.** Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.
- (1) **Operation under the ownership and control of the main provider.** The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:
 - (i) The business enterprise that constitutes the facility or organization is 100 percent owned by the main provider.
 - (ii) The main provider and the facility or organization seeking status as a department of the main provider, a remote location of a hospital, or a satellite facility have the same governing body.
 - (iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.
 - (iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.
 - (2) **Administration and supervision.** The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:
 - (i) The facility or organization is under the direct supervision of the main provider.
 - (ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity -

- (A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and
 - (B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.
- (iii) The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are -
- (A) Contracted out under the same contract agreement; or
 - (B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.
- (3) **Location.** The facility or organization meets the requirements in paragraph (e)(3)(i), (e)(3)(ii), (e)(3)(iii), (e)(3)(iv), (e)(3)(v), or, in the case of an RHC, paragraph (e)(3)(vi) of this section, and the requirements in paragraph (e)(3)(vii) of this section.
- (i) The facility or organization is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider.
 - (ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is -
 - (A) Owned or operated by a unit of State or local government;
 - (B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or
 - (C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).
 - (iii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period -
 - (A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider; or
 - (B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider).
 - (iv) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(iii)(A) or paragraph (e)(3)(iii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(iii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(iii) of this section, accounted for at least 75 percent of the patients served by the main provider.
 - (v) The facility or organization meets all of the following criteria:
 - (A) The facility or organization is seeking provider-based status with respect to a hospital that meets the criteria in § 412.23(d) for reimbursement under Medicare as a children's hospital;
 - (B) The facility or organization meets the criteria for identifying intensive care type units set forth in the Medicare reasonable cost reimbursement regulations under § 413.53(d).
 - (C) The facility or organization accepts only patients who are newborn infants who require intensive care on an inpatient basis.

- (D) The hospital in which the facility or organization is physically located is in a rural area as defined in § 412.64(b)(1)(ii)(C) of this chapter.
- (E) The facility or organization is located within a 100-mile radius of the children's hospital that is the potential main provider.
- (F) The facility or organization is located at least 35 miles from the nearest other neonatal intensive care unit.
- (G) The facility or organization meets all other requirements for provider-based status under this section.
- (vi) Both of the following criteria are met:
 - (A) The facility or organization is an RHC that is otherwise qualified as a provider-based entity of a hospital that has fewer than 50 beds, as determined under § 412.105(b) of this chapter; and
 - (B) The hospital with which the facility or organization has a provider-based relationship is located in a rural area, as defined in § 412.64(b)(1)(ii)(C) of this subchapter.
- (vii) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.
- (f) **Provider-based status for joint ventures.** In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must -
 - (1) Be partially owned by at least one provider'
 - (2) Be located on the main campus of a provider who is a partial owner;
 - (3) Be provider-based to that one provider whose campus on which the facility or organization is located; and
 - (4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.
- (g) **Obligations of hospital outpatient departments and hospital-based entities.** To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:
 - (1) The following departments must comply with the antidumping rules of §§ 489.20(l), (m), (q), and (r) and 489.24 of this chapter:
 - (i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and
 - (ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.
 - (2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of this chapter.
 - (3) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.
 - (4) Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions in § 489.10(b) of this chapter.
 - (5) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.
 - (6) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at § 412.2(c)(5) of this chapter and at § 413.40(c)(2), respectively.

- (7) When a Medicare beneficiary is treated in a hospital outpatient department that is not located on the main provider's campus, the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, and the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, the following requirements must be met:
- (i) The hospital must provide written notice to the beneficiary, before the delivery of services, of -
 - (A) The amount of the beneficiary's potential financial liability; or
 - (B) If the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based, an estimate based on typical or average charges for visits to the facility, and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital.
 - (ii) The notice must be one that the beneficiary can read and understand.
 - (iii) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.
 - (iv) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of § 489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.
- (8) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.
- (h) **Management contracts.** A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:
- (1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of "leased" employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.
 - (2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.
 - (3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.
 - (4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.
- (i) **Furnishing all services under arrangement.** A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.
- (j) **Inappropriate treatment of a facility or organization as provider-based -**
- (1) **Determination and review.** If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS will -
 - (i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this section, and continue payments to the provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and
 - (ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at

the facility or organization for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889 of this chapter.

- (2) **Exception for good faith effort.** CMS will not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if, during all of that period -
 - (i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;
 - (ii) All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and
 - (iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.
- (3) **Notice to provider.** If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.
- (4) **Adjustment of payments.** If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.
- (5) **Continuation of payment.**
 - (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility.
 - (ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.
 - (iii) If the provider indicates that it will be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners -
 - (A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and
 - (B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.
 - (v) If the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.
- (k) **Temporary treatment as provider-based.** If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.
- (l) **Correction of errors.**

- (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did report to CMS under paragraph (c) of this section, treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.
 - (2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.
- (m) **Status of Indian Health Service and Tribal facilities and organizations.** Facilities and organizations operated by the Indian Health Services and Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if they furnish only services that are billed, using the CCN of the main provider and with the consent of the main provider, as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:
- (1) Owned and operated by the Indian Health Service;
 - (2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes; or
 - (3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.
- (n) **FQHCs and "look alikes."** A facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in this section, if the facility -
- (1) Received a grant on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000 under section 330 of the Public Health Service Act under a contract with the beneficiary of such a grant, and continues to meet the requirements to receive a grant under section 330 of the Public Health Service Act; or
 - (2) Based on the recommendation of the Public Health Service, was determined by CMS on or before April 7, 2000 to meet the requirements for receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements.
- (o) **Effective date of provider-based status -**
- (1) **General rule.** Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.
 - (2) **Inappropriate treatment as provider-based or not reporting material change.** Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part

- (4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.
- (c) **Communication plan.** The RHC or FQHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:
- (1) Names and contact information for the following:
 - (i) Staff.
 - (ii) Entities providing services under arrangement.
 - (iii) Patients' physicians.
 - (iv) Other RHCs/FQHCs.
 - (v) Volunteers.
 - (2) Contact information for the following:
 - (i) Federal, State, tribal, regional, and local emergency preparedness staff.
 - (ii) Other sources of assistance.
 - (3) Primary and alternate means for communicating with the following:
 - (i) RHC/FQHC's staff.
 - (ii) Federal, State, tribal, regional, and local emergency management agencies.
 - (4) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).
 - (5) A means of providing information about the RHC/FQHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.
- (d) **Training and testing.** The RHC or FQHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.
- (1) **Training program.** The RHC/FQHC must do all of the following:
 - (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles,
 - (ii) Provide emergency preparedness training at least every 2 years.
 - (iii) Maintain documentation of the training.
 - (iv) Demonstrate staff knowledge of emergency procedures.
 - (v) If the emergency preparedness policies and procedures are significantly updated, the RHC/FQHC must conduct training on the updated policies and procedures.
 - (2) **Testing.** The RHC or FQHC must conduct exercises to test the emergency plan at least annually. The RHC or FQHC must do the following:
 - (i) Participate in a full-scale exercise that is community-based every 2 years; or
 - (A) When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or.
 - (B) If the RHC or FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC or FQHC is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.
 - (ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following:
 - (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or
 - (B) A mock disaster drill; or
 - (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
 - (iii) Analyze the RHC or FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC or FQHC's emergency plan, as needed.

- (e) **Integrated healthcare systems.** If a RHC/FQHC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the RHC/FQHC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:
- (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
 - (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
 - (3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.
 - (4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:
 - (i) A documented community-based risk assessment, utilizing an all-hazards approach.
 - (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.
 - (5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64041, Sept. 16, 2016, as amended by 84 FR 51832, Sept. 30, 2019]



Rural Health Clinic



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What's Changed?

- We pay Rural Health Clinics (RHCs) a bundled payment, or All-Inclusive Rate (AIR) per visit, for qualified primary care and preventive health services provided by an RHC practitioner (page 6)
- Added hospices as a location where RHC visits can take place (page 7)
- Beginning January 1, 2022, RHCs can bill Transitional Care Management (TCM) and general care management services furnished for the same patient during the same service period, if the RHC meets the requirements for billing each code (page 8)
- Beginning April 1, 2021, RHCs will receive a prescribed national statutory payment limit per visit increase over an 8-year period for each year from 2021 through 2028 (page 8)
- Added COVID-19 monoclonal antibody products as services Medicare covers (page 8)
- Beginning January 1, 2022, RHCs can report and get payment for mental health visits furnished via real-time telecommunication technology (page 9)
- Beginning January 1, 2022, RHCs are eligible to get payment for hospice attending physician services when provided by a RHC physician, nurse practitioner, or physician assistant who's employed or working under contract for an RHC, but isn't employed by a hospice program (page 10)

You'll find substantive content updates in dark red font.

A Rural Health Clinic (RHC) is a clinic located in a rural, underserved area with a shortage of primary care providers, personal health services, or both. Currently, there are about 4,500 RHCs nationwide providing primary care and preventive health services in underserved rural areas.

Together we can advance health equity and help eliminate health disparities in rural populations. Find these resources and more from the [CMS Office of Minority Health](#):

- [Rural Health](#)
- [Data Stratified by Geography \(Rural/Urban\)](#)
- [Health Equity Technical Assistance Program](#)

RHC Practitioners

RHCs and their staff must comply with all licensure and certification laws and regulations. Medicare pays RHCs for qualified primary and preventive health services provided by RHC practitioners, including:

- Physicians
- Nurse Practitioners (NPs)
- Physician Assistants (PAs)
- Certified Nurse-Midwives (CNMs)
- Clinical Psychologists (CPs)
- Clinical Social Workers (CSWs)

RHC Patient Services

RHCs provide:

- Primary care and preventive services
- Services and supplies furnished incident to RHC practitioner services, such as taking blood pressure or administering shots
- Homebound visiting nurse services in CMS-certified home health agency shortages
- Some care management services
- Some [virtual communication services](#), such as communications-based technology and remote evaluation services

RHC Certification

To be certified as an RHC, a clinic must meet all state and federal requirements, including location, staffing, and health care services requirements. RHCs must also have a quality assessment and program improvement program.

Location Requirements

An RHC must:

- Be located in an area defined by the U.S. Census Bureau as non-urbanized
- Be located in an area currently designated by the Health Resources and Services Administration (HRSA) within the last 4 years as 1 of these:
 - Primary Care Geographic Health Professional Shortage Area
 - Primary Care Population-Group Health Professional Shortage Area
 - Medically Underserved Area
 - Governor-designated and Secretary-certified Shortage Area

Staffing Requirements

An RHC must:

- Employ an NP or PA (RHCs may contract with NPs, PAs, CNMs, CPs, and CSWs when the RHC employs at least 1 NP or PA)
- Have an NP, PA, or CNM working at least 50% of the time during operational hours
- Post operation days and hours

Health Care Services Requirements

An RHC must:

- Directly provide routine diagnostic and lab services
- Have arrangements with 1 or more hospitals to provide medically necessary services unavailable at the RHC
- Have drugs and biologicals available to treat emergencies
- Provide these lab tests on site:
 - Stick or tablet chemical urine exam or both
 - Hemoglobin or hematocrit
 - Blood sugar
 - Occult blood stool specimens exam

- Pregnancy tests
- Primary culturing to send to a certified lab
- Not be primarily a mental disease treatment facility or a rehabilitation agency
- Not be a Federally Qualified Health Center (FQHC)

RHC Payments

We pay RHCs a bundled payment, or All-Inclusive Rate (AIR) **per visit**, for qualified primary care and preventive health services an RHC practitioner provides. **We subject the AIR to a payment limit per visit, meaning an RHC won't get any payment beyond the specified limit amount per visit.**

For independent RHCs, provider-based RHCs in a hospital with 50 or more beds, and RHCs enrolled in Medicare on or after January 1, 2021:

- Payment limit per visit based on these national statutory limits:
 - January 1, 2021–March 31, 2021 = \$87.52
 - April 1, 2021–December 31, 2021 = \$100.00
 - Calendar Year (CY) 2022 = \$113.00

For specified provider-based RHCs in a hospital with less than 50 beds:

- Medicare Administrative Contractors (MACs) calculate the payment limit per visit for provider-based RHCs that meet certain criteria

For certain preventive services like the Annual Wellness Visit (AWV) and the Initial Preventive Physical Exam (IPPE), we pay the full AIR and patients don't pay anything. For most other services, Medicare Part B deductible and coinsurance rates apply. This means that once patients meet their Part B deductible, we pay 80% of the AIR and the patient pays the remaining 20%.



RHC Visits

RHC visits must be:

- Medically necessary
- Medical or mental health visits, qualified preventive health visits, or face-to-face visits between the patient and an RHC practitioner
- A qualified RHC service needing an RHC practitioner

RHC visits **can** take place at:

- RHC
- Patient's home, including an assisted living facility
- Medicare-covered Part A skilled nursing facility
- Scene of an accident
- **Hospice**

RHC visits **can't** take place at:

- Inpatient or outpatient hospital department, including a critical access hospital
- Facility with specific requirements excluding RHC visits

Multiple Visits on the Same Day

Visits with more than 1 RHC practitioner on the same day, or multiple visits with the same RHC practitioner on the same day, count as a single visit, **except** when:

- Patient returns to the RHC for diagnosis or treatment of an injury or illness that happened after the initial visit; for example, a patient sees their practitioner in the morning because they have flu symptoms, then later in the day they cut their finger and return to the RHC
- Patient has a qualified medical and mental health visit on the same day
- Patient has an IPPE and a separate medical or mental health visit on the same day

RHC Services

Care Management Services

RHCs may provide general care management services, such as:

- Transitional Care Management (TCM)
 - Beginning January 1, 2022, RHCs can bill TCM and general care management services furnished for the same patient during the same service period, if the RHC meets the requirements for billing each code
- General Care Management (G0511)
 - Chronic Care Management (CCM)
 - General Behavioral Health Integration (BHI)
 - Principal Care Management (PCM)
- Psychiatric Collaborative Care Model (CoCM) (G0512)

We don't require the RHC face-to-face services requirement for care management services. Auxiliary personnel may provide them under general supervision.

RHCs can't bill care management services if another practitioner or facility billed them during the same time period.

Flu, Pneumococcal, & COVID-19 Shots & COVID-19 Monoclonal Antibody Products

We pay for flu, pneumococcal, COVID-19 shots, and COVID-19 monoclonal antibody products and their administration at 100% of reasonable cost. RHCs report these services on a separate cost report worksheet. RHCs shouldn't report these services on their RHC billing claims.

Note: We updated the RHC cost report to reflect costs related to COVID-19 shots and COVID-19 monoclonal antibody products and their administration.

An RHC can't bill a visit when the practitioner only sees a patient to administer a shot. Instead, the RHC includes shots and their administration on the annual cost report and we reimburse them at cost settlement. Patients pay no Part B deductible or coinsurance for these services.

Hepatitis B Shot Administration & Payment

The bundled payment, or AIR, for an RHC visit includes the hepatitis B shot and its administration costs. This means you can't bill the shot or its administration separately from the visit, and you can't bill for a visit if shot administration is the only service you provided. However, you can include it on a separate line item when you submit the visit's bill, which ensures the patient pays no deductible or coinsurance. If the shot was the only service you provided, you can add it on a separate line item for the next visit.

Telehealth Services Payment

RHCs can be an “originating site” for telehealth services. An originating site is the location where an eligible patient gets telehealth services. A patient must go to an originating site for services located in a county outside a Metropolitan Statistical Area or in a rural Health Professional Shortage Area in a rural census tract. RHCs serving as telehealth originating sites get an originating site facility fee. You may include the originating site facility fee charges on the claim.

RHCs aren’t authorized to serve as a “distant sites,” except during the COVID-19 Public Health Emergency (PHE) (see [COVID-19 Flexibilities](#)). A distant site is where the practitioner is located during the telehealth service. You can’t bill the visit’s cost or include it on the cost report.

This means patients can go to the RHC to get telehealth services provided by practitioners located in other areas of the state or country, but practitioners in the RHC can’t provide telehealth services, except during the COVID-19 PHE.

Mental Health Visits Furnished Using Telehealth

Beginning January 1, 2022, RHCs can report and get payment for mental health visits furnished via real-time telecommunication technology in the same way they currently do when visits take place in-person, including audio-only visits when the patient isn’t capable of, or doesn’t consent to, using video technology.

An in-person, non-telehealth visit must be furnished at least every 12 months for these services; however, we may make exceptions to the in-person visit requirement based on patient circumstances (with the reason documented in the patient’s medical record) and also allow more frequent visits as driven by clinical needs on a case-by-case basis.

Virtual Communication Services (G0071)

We pay for virtual communication services when an RHC practitioner meets certain requirements, including:

- Practitioner provides at least 5 minutes of billable RHC communication technology-based or remote evaluation service
- Patient had at least 1 face-to-face billable visit within previous year
- Virtual visit isn’t related to service provided within last 7 days
- Virtual visit doesn’t lead to in-person RHC service within the next 24 hours or at next appointment

When an RHC practitioner provides a patient with virtual communication service, we don’t require the RHC face-to-face requirements and apply the [coinsurance and deductible](#).

[Virtual Communication Services FAQs](#) has more information.

Hospice Attending Physician Services Payment

Beginning January 1, 2022, RHCs and FQHCs will be eligible to get payment for hospice attending physician services when provided by an RHC physician, NP, or PA who's employed or working under contract for an RHC, but isn't employed by a hospice program. During a hospice election, attending physician services can take place at the patient's home, a Medicare-certified hospice freestanding facility, skilled nursing facility, or hospital.

COVID-19 Flexibilities

[MLN Matters® Article SE20016](#) has more information on new and expanded COVID-19 RHC flexibilities during the PHE.

Cost Reports

RHCs must file an annual cost report. Use [Form CMS-222-17](#) to determine your payment rate and reconcile interim payments. Include graduate medical education adjustments, bad debt, shots, and their administration payments.

- Independent RHCs must complete [Health Clinic Form \(CMS-222-1992\)](#), Independent Rural Health Clinic and Freestanding Federally Qualified Health Center (HCLINIC) Cost Report
- Hospital-based RHCs must complete [Hospital Form \(CMS-2552-2010\)](#), Worksheet M, Hospital and Hospital Health Care Complex Cost Report
- Provider-based RHCs must complete the appropriate worksheet for RHC services within the parent provider's cost report

[Provider Reimbursement Manual – Part 2](#) has more cost reports and forms.

Annual Reconciliation

At the end of the annual cost reporting period, RHCs submit a report to their MACs. The report includes total allowable costs, total RHC service visits, and other required reporting period information. After reviewing the report, MACs determine a final period rate by dividing allowable costs by the number of actual visits.

MACs determine the total payment due and the amount necessary to reconcile payments made during the period with the total payment due. They review interim and final payment rates for productivity, reasonableness, and payment limitations.

For more information, [find your MAC's website](#).

Resources

- Learn about covered services, visits, payment policies, and other information in [Medicare Benefit Policy Manual, Chapter 13](#)
- Learn how we process RHC claims in [Medicare Claims Processing Manual, Chapter 9](#)
- Learn how we evaluate state survey and certification efforts in [State Operations Manual, Chapter 8](#)
- Learn about RHC certification requirements in [Medicare State Operations Manual, Chapter 2, Appendix G](#)
- Learn about being certified as a Medicare RHC supplier by reviewing [applicable laws, regulations, and compliance information](#)
- Learn how RHC providers did on performance surveys by searching [Survey and Certification's Quality, Certification and Oversight Reports \(QCOR\)](#)
- Find more information about billing care management services in the [Care Management Services in RHCs and FQHCs FAQs](#)

Other Helpful Websites

- [American Hospital Association Rural Health Services](#)
- [CMS's Rural Health Strategy](#)
- [Medicare Rural Health Clinics](#)
- [National Association of Rural Health Clinics](#)
- [National Rural Health Association](#)
- [Rural Health Information Hub](#)

Regional Office Rural Health Coordinators

Get contact information for [CMS Regional Office Rural Health Coordinators](#) who offer technical, policy, and operational help on rural health issues.

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Medicare Benefit Policy Manual

Chapter 13 - Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services

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(Rev. 10729, 04-26-21)

AIR – all inclusive rate
AWV – annual wellness visit
BHI – behavioral health integration
CCM – chronic care management
CCN – CMS certification number
CNM – certified nurse midwife
CoCM – collaborative care model
CP – clinical psychologist
CSW – clinical social worker
DSMT – diabetes self-management training
EKG – electrocardiogram
E/M – evaluation and management
FQHC – Federally qualified health center
FTE – full time equivalent
GAF – geographic adjustment factor
GME – graduate medical education
HCPCS – Healthcare Common Procedure Coding System
HHA – home health agency
HHS – Health and Human Services
HPSA – Health Professional Shortage Area
HRSA – Health Resources and Services Administration
IPPE – initial preventive physical exam
LDTC – low dose computed tomography
LPN – licensed practical nurse
MAC – Medicare Administrative Contractor
MEI – Medicare Economic Index
MNT – medical nutrition therapy
MSA – metropolitan statistical area
MUA – Medically-Underserved Area
MUP – Medically-Underserved Population

NCD – national coverage determination

NECMA – New England County Metropolitan Area

NP – nurse practitioner

OBRA - Omnibus Budget Reconciliation Act

PA – physician assistant

PCE - Primary Care Exception

PCM – Principal Care Management

PFS – physician fee schedule

PPS – prospective payment system

PHS – Public Health Service

RHC – rural health clinic

RN – registered nurse

RO – regional office

RUCA – Rural Urban Commuting Area

SLP – speech language therapy

TCM – transitional care management

UA – urbanized area

USPSTF – U.S. Preventive Services Task Force

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10 - RHC and FQHC General Information

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

10.1 - RHC General Information

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Rural Health Clinics (RHCs) were established by the Rural Health Clinic Service Act of 1977 to address an inadequate supply of physicians serving Medicare beneficiaries in underserved rural areas, and to increase the utilization of nurse practitioners (NP) and physician assistants (PA) in these areas. RHCs have been eligible to participate in the Medicare program since March 1, 1978, and are paid an all-inclusive rate (AIR) for medically-necessary primary health services, and qualified preventive health services, furnished by an RHC practitioner.

RHCs are defined in section 1861(aa)(2) of the Social Security Act (the Act) as facilities that are engaged primarily in providing services that are typically furnished in an outpatient clinic. RHC services are defined as:

- Physician services;
- Services and supplies furnished incident to a physician's services;
- NP, PA, certified nurse midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW) services; and
- Services and supplies furnished incident to an NP, PA, CNM, or CP services.

RHC services may also include nursing visits to patients confined to the home that are furnished by a registered professional nurse (RN) or a licensed professional nurse (LPN) when certain conditions are met. (See section 190 of this manual)

To be eligible for certification as an RHC, a clinic must be located in a non-urbanized area, as determined by the U.S. Census Bureau, and in an area designated or certified within the previous 4 years by the Secretary, Health and Human Services (HHS), in any one of the four types of shortage area designations that are accepted for RHC certification. (See section 20 of this manual)

In addition to the location requirements, an RHC must:

- Employ an NP or PA;

- Have an NP, PA, or CNM working at the clinic at least 50 percent of the time the clinic is operating as an RHC;
- Directly furnish routine diagnostic and laboratory services;
- Have arrangements with one or more hospitals to furnish medically necessary services that are not available at the RHC;
- Have available drugs and biologicals necessary for the treatment of emergencies;
- Meet all health and safety requirements;
- Not be a rehabilitation agency or a facility that is primarily for mental health treatment;
- Furnish onsite all of the following six laboratory tests:
 - Chemical examination of urine by stick or tablet method or both;
 - Hemoglobin or hematocrit;
 - Blood sugar;
 - Examination of stool specimens for occult blood;
 - Pregnancy tests; and
 - Primary culturing for transmittal to a certified laboratory.
- Not be concurrently approved as an FQHC, and
- Meet other applicable State and Federal requirements.

RHCs can be either independent or provider-based. Independent RHCs are stand-alone or freestanding clinics and submit claims to a Medicare Administrative Contractor (A/B MAC). They are assigned a CMS Certification Number (CCN) in the range 3800-3974 or 8900-8999. Provider-based RHCs are an integral and subordinate part of a hospital (including a critical access hospital (CAH)), skilled nursing facility (SNF), or a home health agency (HHA). They are assigned a CCN in the range 3400-3499, 3975-3999, or 8500-8899. (**NOTE:** A provider-based CCN is not an indication that the RHC has a provider-based determination for purposes of an exception to the payment limit.)

The statutory requirements for RHCs are found in section 1861(aa) of the Act. Many of the regulations pertaining to RHCs can be found at 42 CFR 405.2400 Subpart X and following, and 42 CFR 491 Subpart A and following.

For information on claims processing, see Pub. 100-04, Medicare Claims Processing Manual, chapter 9, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c09.pdf>.

For information on certification requirements, see Pub. 100-07, Medicare State Operations Manual, Chapter 2, and Appendix G, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf

10.2 - FQHC General Information

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Federally Qualified Health Centers (FQHCs) were established in 1990 by section 4161 of the Omnibus Budget Reconciliation Act (OBRA) of 1990 and were effective beginning on October 1, 1991. As with RHCs, they are also facilities that are primarily engaged in providing services that are typically furnished in an outpatient clinic. FQHCs were paid an AIR for primary health services and qualified preventive health services until October 1, 2014, when they began to transition to the FQHC prospective payment system (PPS). Beginning on January 1, 2016, all FQHC are paid under the provisions of the FQHC PPS, as required by Section 10501(i)(3)(B) of the Affordable Care Act.

FQHC services are defined as:

- Physician services;
- Services and supplies furnished incident to a physician's services;
- NP, PA, certified nurse midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW) services;
- Services and supplies furnished incident to an NP, PA, CNM, or CP services; and
- Outpatient diabetes self-management training (DSMT) and medical nutrition therapy (MNT) for beneficiaries with diabetes or renal disease.

The statutory requirements that FQHCs must meet to qualify for the Medicare benefit are in section 1861(aa)(4) of the Act. No Part B deductible is applied to expenses for

services that are payable under the FQHC benefit. An entity that qualifies as an FQHC is assigned a CCN in the range 1800-1989 and 1000-1199.

FQHC services also include certain preventive primary health services. The law defines Medicare-covered preventive services provided by an FQHC as the preventive primary health services that an FQHC is required to provide under section 330 of the Public Health Service (PHS) Act. Medicare may not cover some of the preventive services that FQHCs provide, such as dental services, which are specifically excluded under Medicare law.

There are 3 types of organizations that are eligible to enroll in Medicare as FQHCs:

- Health Center Program Grantees: Organizations receiving grants under section 330 of the PHS Act, including Community Health Centers, Migrant Health Centers, Health Care for the Homeless Health Centers, and Public Housing Primary Care Centers;
- Health Center Program Look-Alikes: Organizations that have been identified by HRSA as meeting the definition of “Health Center” under section 330 of the PHS Act, but not receiving grant funding under section 330; and
- Outpatient health programs/facilities operated by a tribe or tribal organization (under the Indian Self-Determination Act) or by an urban Indian organization (under Title V of the Indian Health Care Improvement Act).

NOTE: Information in this chapter applies to FQHCs that are Health Center Program Grantees and Health Center Program Look-Alikes. It does not necessarily apply to tribal or urban Indian FQHCs or grandfathered tribal FQHCs.

An FQHC must:

- Provide comprehensive services and have an ongoing quality assurance program;
- Meet other health and safety requirements;
- Not be concurrently approved as an RHC; and

- Meet all requirements contained in section 330 of the Public Health Service Act, including:
 - Serve a designated Medically-Underserved Area (MUA) or Medically-Underserved Population (MUP);
 - Offer a sliding fee scale to persons with incomes below 200 percent of the federal poverty level; and
 - Be governed by a board of directors, of whom a majority of the members receive their care at the FQHC.

Additional information on these and other section 330 requirements can be found at <http://bphc.hrsa.gov/>.

Per 42 CFR 413.65(n), only FQHCs that were operating as provider-based clinics prior to 1995 and either a) received funds under section 330 of the PHS Act or b) were determined by CMS to meet the criteria to be a look-alike clinic, are eligible to be certified as provider-based FQHCs. Clinics that do not already have provider-based status as an FQHC are no longer permitted to receive the designation.

For information on claims processing, see to Pub. 100-04, Medicare Claims Processing Manual, chapter 9, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c09.pdf>, and Pub. 100-07, State Operations Manual chapter 2, sections 2825 and 2826, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf>.

20 - RHC and FQHC Location Requirements

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

To be eligible for certification as an RHC, a clinic must be located in 1) a non-urbanized area, as determined by the U.S. Census Bureau, and 2) an area designated or certified within the previous 4 years by the Secretary, HHS, in any one of the four types of shortage area designations that are accepted for RHC certification as listed in section 20.2.

A clinic applying to become a Medicare-certified RHC must meet both the rural and underserved location requirements. Mobile clinics must have a fixed schedule that specifies the date and location for services, and each location must meet the location requirements.

Existing RHCs are not currently required to continue to meet the location requirements. RHCs that plan to relocate or expand should contact their Regional Office (RO) to determine their location requirements.

FQHCs may be located in rural or urban areas. FQHCs that are Health Center Program Grantees or Look-Alikes must be located in or serve people from a HRSA-designated MUA or MUP.

20.1 - Non-Urbanized Area Requirement for RHCs

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

The U.S. Census Bureau determines if an area is an urbanized area (UA). Any area that is not in a UA is considered a non-urbanized area. A clinic located in an area that is not a UA would meet the RHC requirement for being in a non-urbanized area. Information on whether an area is in an urbanized area can be found at <http://factfinder.census.gov>; or <http://www.raconline.org>; or by contacting the appropriate CMS RO at <http://www.cms.gov/RegionalOffices/>.

20.2 - Designated Shortage Area Requirement for RHCs

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

The HRSA designates areas as MUAs/MUPs and/or Health Professional Shortage Areas (HPSAs). To be eligible for RHC certification, a clinic must be located in an area that has one of the following types of shortage area designations:

- Geographic Primary Care HPSA;
- Population-group Primary Care HPSA;
- MUA (this does not include the population group MUP designation); or
- Governor-Designated and Secretary-Certified Shortage Area (this does not include a Governor's Medically Underserved Population designation).

No other type of shortage area designation is accepted for purposes of RHC certification. The designation cannot be more than 4 years old in order to meet the requirement of being in a currently designated area. For RHC purposes, the age of the designation is calculated as the last day of the year 4 years from the date of the original designation, or the date the area was last designated. For example, a clinic that is located in an area that was most recently designated or updated on June 1, 2010, would be considered as meeting this location requirement through December 31, 2014.

Areas that are listed as “proposed for withdrawal” are considered designated. The designation date is the date that the area was last updated, not when the area was proposed for withdrawal. To determine the designation date of an area that is listed as “proposed for withdrawal”, contact HRSA’s Shortage Designation Branch at sdb@hrsa.gov or call 1-888-275-4772.

30 - RHC and FQHC Staffing Requirements

(Rev. 166, Issued: 01-31-13, Effective: 03-01-13, Implementation: 03-01-13)

30.1 - RHC Staffing Requirements

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

In addition to the location requirements, an RHC must:

- Employ an NP or PA; and
- Have an NP, PA, or CNM working at the clinic at least 50 percent of the time the clinic is operating as an RHC.

The employment may be full or part time, and is evidenced by a W-2 form from the RHC. If another entity such as a hospital has 100 percent ownership of the RHC, the W-2 form can be from that entity as long as all the non-physician practitioners employed in the RHC receive their W-2 from this owner.

The following are examples of situations that would NOT satisfy the employment requirement:

- An NP or PA who is employed by a hospital that has an ownership interest in the RHC but is not physically present and working in the RHC;
- A CNM who is employed by the RHC;
- An Advanced Practice Registered Nurse who is not an NP or PA; or
- An NP or PA who is working as a substitute in an arrangement similar to a locum tenens physician.

An RHC practitioner is a physician, NP, PA, CNM, CP, or CSW. At least one of these practitioners must be present in the RHC and available to furnish patient care at all times the RHC is in operation. A clinic that is open solely to address administrative matters or to provide shelter from inclement weather is not considered to be in operation during this period and is not subject to the staffing requirements.

An NP, PA, or CNM must be available to furnish patient care at least 50 percent of the time that the RHC is open to provide patient care. This requirement can be fulfilled through any combination of NPs, PAs, or CNMs as long as the total is at least 50 percent of the time the RHC is open to provide patient care. Only the time that an NP, PA, or CNM spends in the RHC, or the time spent directly furnishing patient care in another location as an RHC practitioner, is counted towards the 50 percent time. It does not include travel time to another location, or time spent not furnishing patient care when in another location outside the RHC (e.g. home, SNF, etc.).

A clinic located on an island that otherwise meets the requirements for RHC certification is not required to employ an NP or PA, although it is still required to have an NP or PA at least 50 percent of the time that the RHC is in operation (OBRA '89, Sec 4024). An island is a body of land completely surrounded by water, regardless of size and accessibility (e.g., bridges).

As of July 1, 2014, RHCs may contract with non-physician practitioners (PAs, NPs, CNM, CPs or CSWs) if at least one NP or PA is employed by the RHC (subject to the waiver provision for existing RHCs set forth at section 1861(aa)(7) of the Act).

It is the responsibility of the RHC to assure that all staffing requirements are met and that RHC practitioners provide services in accordance with state and federal laws and regulations.

See section 80.4 of this chapter for information on productivity standards for RHCs.

30.2 - RHC Temporary Staffing Waivers (Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

An existing RHC may request a temporary staffing waiver if the RHC met the staffing requirements before seeking the waiver, and either or both of the following occur:

- An NP or PA is not currently employed by the RHC.
- An NP, PA, or CNM is not furnishing patient care at least 50 percent of the time the RHC operates.

To receive a temporary staffing waiver, an RHC must demonstrate that it has made a good faith effort to recruit and retain the required practitioner(s) in the 90 day period prior to the waiver request. Recruitment activities should begin as soon as the RHC becomes aware that they will no longer be in compliance with this requirement. Good faith efforts can include activities such as advertising in an appropriate newspaper or professional journal, conducting outreach to an NP, PA, or CNM school, or other activities.

Staffing waivers are for a period not to exceed 1 year. The waiver cannot be extended beyond 1 year, and another waiver cannot be granted until a minimum of 6 months have elapsed since the prior waiver expired. RHCs should continue their recruitment activities during the waiver period to avoid termination when the waiver period ends.

An RHC will be terminated if any of the following occur:

- The RHC does not meet the staffing requirements and does not request a temporary staffing waiver;
- The RHC requests a temporary staffing waiver and the request is denied due to a lack of good faith effort to meet the requirements;
- The RHC does not meet the staffing requirements and is not eligible for a temporary staffing waiver because less than 6 months have passed since the expiration of the previous waiver;
- The RHC reaches the expiration date of the temporary staffing waiver and has not come into compliance; or
- Other non-compliance issue.

30.3 - FQHC Staffing Requirements

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

FQHCs must have a core staff of appropriately trained primary care practitioners and meet other clinical requirements. It is the responsibility of the FQHC to assure that all staffing requirements are met and that FQHC practitioners provide services in accordance with State and Federal laws and regulations. Additional information on FQHC staffing requirements can be found at: <http://bphc.hrsa.gov/about/requirements/index.html>.

40 - RHC and FQHC Visits

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

An RHC or FQHC visit is a medically-necessary medical or mental health visit, or a qualified preventive health visit. The visit must be a face-to-face (one-on-one) encounter between the patient and a physician, NP, PA, CNM, CP, or a CSW during which time one or more RHC or FQHC services are rendered. A Transitional Care Management (TCM) service can also be an RHC or FQHC visit. Services furnished must be within the practitioner's state scope of practice, and only services that require the skill level of the RHC or FQHC practitioner are considered RHC or FQHC visits.

An RHC or FQHC visit can also be a visit between a home-bound patient and an RN or LPN under certain conditions. See section 190 of this chapter for information on visiting nursing services to home-bound patients.

Under certain conditions, an FQHC visit also may be provided by qualified practitioners of outpatient DSMT and MNT when the FQHC meets the relevant program requirements for provision of these services.

RHC and FQHC visits are typically evaluation and management (E/M) type of services or screenings for certain preventive services. A list of qualifying visits for FQHCs is located on the FQHC web page at <https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html>.

40.1 – Location

(Rev. 252, Issued: 12- 07-18, Effective: 01-01-19, Implementation: 01- 02-19)

RHC or FQHC visits may take place in:

- the RHC or FQHC,
- the patient's residence (including an assisted living facility),
- a Medicare-covered Part A SNF (see Pub. 100-04, Medicare Claims Processing Manual, chapter 6, section 20.1.1), or
- the scene of an accident.

RHC and FQHC visits may not take place in:

- an inpatient or outpatient department of a hospital, including a CAH, or
- a facility which has specific requirements that preclude RHC or FQHC visits (e.g., a Medicare comprehensive outpatient rehabilitation facility, a hospice facility, etc.).

Qualified services provided to a RHC or FQHC patient are considered RHC or FQHC services if:

- the practitioner is compensated by the RHC or FQHC for the services provided;
- the cost of the service is included in the RHC or FQHC cost report; and;
- other requirements for furnishing services are met.

This applies to full and part time practitioners, and it applies regardless of whether the practitioner is an employee of the RHC or FQHC, working under contract to the RHC or FQHC, or is compensated by the RHC or FQHC under another type of arrangement. RHCs and FQHCs should have clear policies regarding the provision of services in other locations and include this in a practitioner's employment agreement or contract. RHCs and FQHCs providing RHC or FQHC services in locations other than the RHC or FQHC facility must continue to meet all certification and cost reporting requirements. Services in other locations may be subject to review by the A/B MAC. RHC or FQHC services furnished by an RHC or FQHC practitioner may not be billed separately by the RHC or FQHC practitioner, or by another practitioner or an entity other than the RHC or FQHC, even if the service is not a stand-alone billable visit. Services furnished to patients in any

type of hospital setting (inpatient, outpatient, or emergency department) are statutorily excluded from the RHC/FQHC benefit and may not be billed by the RHC or FQHC.

40.2 - Hours of Operation

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

RHCs and FQHCs are required to post their hours of operations at or near the entrance in a manner that clearly states the days of the week and the hours that RHC or FQHC services are furnished, and days of the week and the hours that the building is open solely for administrative or other purposes, if applicable. This information should be easily readable, including by people with vision problems and people who are in wheel chairs. Qualified services provided to an RHC or FQHC patient other than during the posted hours of operation are considered RHC or FQHC services when the practitioner is compensated by the RHC or FQHC for the services provided, and when the cost of the service is included in the RHC's cost report.

Services furnished at times other than the RHC or FQHC posted hours of operation to Medicare beneficiaries who are RHC or FQHC patients may not be billed to Medicare Part B if the practitioner's compensation for these services is included in the RHC/FQHC cost report. (See Section 100 on Commingling).

This applies to full and part time practitioners, practitioners who are employees, practitioners working under contract to the RHC or FQHC, and practitioners who are compensated by the RHC or FQHC under another type of arrangement. RHCs and FQHCs should have clear policies regarding the provision of services at other times, and include this in a practitioner's employment agreement or contract.

40.3 - Multiple Visits on Same Day

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Except as noted below, encounters with more than one RHC or FQHC practitioner on the same day, or multiple encounters with the same RHC or FQHC practitioner on the same day, constitute a single RHC or FQHC visit and is payable as one visit. This policy applies regardless of the length or complexity of the visit, the number or type of practitioners seen, whether the second visit is a scheduled or unscheduled appointment, or whether the first visit is related or unrelated to the subsequent visit. This would include situations where an RHC or FQHC patient has a medically-necessary face-to-face visit with an RHC or FQHC practitioner, and is then seen by another RHC or FQHC practitioner, including a specialist, for further evaluation of the same condition on the same day, or is then seen by another RHC or FQHC practitioner, including a specialist, for evaluation of a different condition on the same day.

Exceptions are for the following circumstances only:

- The patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day (for example, a patient sees their practitioner in the morning for a medical condition and later in the day has a fall and returns to the RHC or FQHC). In this situation only, the FQHC would use modifier 59 on the claim and the RHC would use modifier 59 or 25 to attest that the conditions being treated qualify as 2 billable visits;
- The patient has a qualified medical visit and a qualified mental health visit on the same day (2 billable visits); or
- For RHCs only, the patient has an initial preventive physical exam (IPPE) and a separate medical and/or mental health visit on the same day (2 or 3 billable visits).

NOTE: These exceptions do not apply to grandfathered tribal FQHCs.

40.4 - Global Billing

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Surgical procedures furnished in an RHC or FQHC by an RHC or FQHC practitioner are considered RHC or FQHC services. Procedures are included in the payment of an otherwise qualified visit and are not separately billable. If a procedure is associated with a qualified visit, the charges for the procedure go on the claim with the visit. Payment is included in the AIR when the procedure is furnished in an RHC, and payment is included in the PPS methodology when furnished in an FQHC. The Medicare global billing requirements do not apply to RHCs and FQHCs, and global billing codes are not accepted for RHC or FQHC billing or payment.

Surgical procedures furnished at locations other than RHCs or FQHCs may be subject to Medicare global billing requirements. If an RHC or FQHC furnishes services to a patient who has had surgery elsewhere and is still in the global billing period, the RHC or FQHC must determine if these services have been included in the surgical global billing. RHCs and FQHCs may bill for a visit during the global surgical period if the visit is for a service not included in the global billing package. If the service furnished by the RHC or FQHC was included in the global payment for the surgery, the RHC or FQHC may not also bill for the same service.

Services not included in the global surgical package are listed in Pub. 100-04, Medicare Claims Processing Manual, chapter 12, section 40.1.B, and include, but are not limited to: initial consultation by the surgeon to determine the need for major surgery; visits unrelated to the diagnosis for which the surgical procedure is performed (unless the visit occurs due to complications of the surgery); treatment for the underlying condition or an added course of treatment which is not part of normal recovery from surgery; etc.

For additional information on global billing, see <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>

40.5 - 3-Day Payment Window

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Medicare's 3-day payment window applies to outpatient services furnished by a hospital (or an entity that is wholly owned or wholly operated by the hospital). The statute requires that hospitals' bundle the technical component of all outpatient diagnostic services and related non-diagnostic services (e.g., therapeutic) with the claim for an inpatient stay when services are furnished to a Medicare beneficiary in the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1-day) preceding an inpatient admission in compliance with section 1886 of the Act.

RHCs and FQHC services are not subject to the Medicare 3- day payment window requirements.

For additional information on the 3 day payment window, see <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7502.pdf>

50 - RHC and FQHC Services

(Rev. 166, Issued: 01-31-13, Effective: 03-01-13, Implementation: 03-01-13)

50.1 - RHC Services

(Rev. 252, Issued: 12- 07-18, Effective: 01-01-19, Implementation: 01- 02-19)

RHC services include:

- Physicians' services, as described in section 110;
- Services and supplies incident to a physician's services, as described in section 120;
- Services of NPs, PAs, and CNMs, as described in section 130;
- Services and supplies incident to the services of NPs, PAs, and CNMs, as described in section 140;
- CP and CSW services, as described in section 150;
- Services and supplies incident to the services of CPs, as described in section 160; and
- Visiting nurse services to patients confined to the home, as described in section 190.
- Certain care management services, as described in section 230.
- Certain virtual communication services, as described in section 240.

RHC services also include certain preventive services when specified in statute or when established through the National Coverage Determination (NCD) process and not

specifically excluded (see section 220 – Preventive Health Services). These services include:

- Influenza, Pneumococcal, Hepatitis B vaccinations;
- IPPE;
- Annual Wellness Visit (AWV); and
- Medicare-covered preventive services recommended by the U.S. Preventive Services Task Force (USPSTF) with a grade of A or B, as appropriate for the individual.

Influenza and pneumococcal vaccines and their administration are paid through the cost report, and payment for the hepatitis B vaccine and its administration is included in an otherwise billable visit. The professional component of the IPPE, AWV, and other qualified preventive services is paid based on the AIR.

50.2 - FQHC Services

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

FQHC services include all of the RHC services listed in section 50.1 of this chapter. While the following services may also be furnished in an RHC, the statute specifically lists certain services as FQHC services, including but not limited to:

- Screening mammography;
- Screening pap smear and screening pelvic exam;
- Prostate cancer screening tests;
- Colorectal cancer screening tests;
- DSMT services;
- Diabetes screening tests;
- MNT services;
- Bone mass measurement;
- Screening for glaucoma;

- Cardiovascular screening blood tests; and
- Ultrasound screening for abdominal aortic aneurysm.

Influenza and pneumococcal vaccines and their administration are paid through the cost report, and payment for the hepatitis B vaccine and its administration is included in an otherwise billable visit. The professional component of the IPPE, AWW, and other qualified preventive services is paid based on the lesser of the FQHC's charge or the PPS rate for the specific payment code, with an adjustment for IPPE and AWW (see section 70.4 – FQHC Payment Codes).

50.3 - Emergency Services

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

RHCs provide outpatient services that are typically furnished in a physician's office or outpatient clinic and generally provide only limited emergency care. Neither independent nor hospital-based RHCs are subject to Emergency Medical Treatment and Active Labor Act regulations. However, RHC practitioners are required to provide medical emergency procedures as a first response to common life threatening injuries and acute illnesses and to have available the drugs and biologicals commonly used in life-saving procedures. The definition of a "first response" is a service that is commonly provided in a physician's office.

If a patient presents at the RHC with an emergency when the RHC is not open for patient care because a physician, NP, PA, CNM, CP, or CSW is not present, other staff may attend to the patient until care of the individual can be transferred. Any care provided in this situation must be within the individual's ability, training, and scope of practice, and in accordance with state laws, and would not be considered an RHC service.

During their regular hours of operations, FQHC practitioners are required to provide medical procedures as a first response to common life threatening injuries and acute illnesses and to have available the drugs and biologicals commonly used in life-saving procedures. After their operating hours, FQHCs must provide telephone access to an individual who has the qualifications and training to exercise professional judgment in assessing a patient's need for emergency medical care, and if appropriate, to refer the patient to an appropriate provider or facility that is open.

Additional information on emergency preparedness requirements for RHCs and FQHCs can be found 42 CFR 491.12.

60 - Non RHC/FQHC Services

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

RHCs and FQHCs must be primarily engaged in furnishing primary care services, but may also furnish certain services that are beyond the scope of the RHC or FQHC benefit,

such as laboratory services or the technical component of an RHC or FQHC service. If these services are authorized to be furnished by the RHC or FQHC and are covered under a separate Medicare benefit category, the services must be billed separately (not by the RHC or FQHC) to the appropriate A/B MAC under the payment rules that apply to the service. RHCs and FQHCs must identify and remove from allowable costs on the Medicare cost report all costs associated with the provision of non-RHC/FQHC services such as space, equipment, supplies, facility overhead, and personnel.

60.1 - Description of Non RHC/FQHC Services

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Certain services are not considered RHC or FQHC services either because they 1) are not included in the RHC or FQHC benefit, or 2) are not a Medicare benefit. Non-RHC/FQHC services include, but are not limited to:

Medicare excluded services - Includes routine physical checkups, dental care, hearing tests, routine eye exams, etc. For additional information, see Pub. 100-02, Medicare Benefit Policy Manual, Chapter 16, General Exclusions from Coverage, at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c16.pdf>

Technical component of an RHC or FQHC service - Includes diagnostic tests such as x-rays, electrocardiograms (EKGs), and other tests authorized by Medicare statute or the NCD process. These services may be billed separately to the A/B MAC by the facility). (The professional component is an RHC or FQHC service if performed by an RHC or FQHC practitioner or furnished incident to an RHC or FQHC visit).

Laboratory services - Although RHCs and FQHCs are required to furnish certain laboratory services (for RHCs see section 1861(aa)(2)(G) of the Act, and for FQHCs see section 330(b)(1)(A)(i)(II) of the PHS Act), laboratory services are not within the scope of the RHC or FQHC benefit. When clinics and centers separately bill laboratory services, the cost of associated space, equipment, supplies, facility overhead and personnel for these services must be adjusted out of the RHC or FQHC cost report. This does not include venipuncture, which is included in the AIR when furnished in an RHC by an RHC practitioner or furnished incident to an RHC service, and it is included in the per-diem payment when furnished in an FQHC by an FQHC practitioner or furnished incident to an FQHC service.

Durable medical equipment - Includes crutches, hospital beds, and wheelchairs used in the patient's place of residence, whether rented or purchased.

Ambulance services - The ambulance transport benefit under Medicare Part B covers a medically necessary transport of a beneficiary by ambulance to the nearest appropriate facility that can treat the patient's condition, and any other methods of transportation are contraindicated. See <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c10.pdf> for additional information on covered ambulance services.

Prosthetic devices - Prosthetic devices are included in the definition of “medical and other health services” in section 1861(s)(8) of the Act and are defined as devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Other examples of prosthetic devices include cardiac pacemakers, cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves.

Body Braces – Includes leg, arm, back, and neck braces and their replacements.

Practitioner services at certain other Medicare facility – Includes services furnished to inpatients or outpatients in a hospital (including CAHs), ambulatory surgical center, Medicare Comprehensive Outpatient Rehabilitation Facility, etc., or other facility whose requirements preclude RHC or FQHC services. (**NOTE:** Covered services provided to a Medicare beneficiary by an RHC or FQHC practitioner in a SNF may be an RHC or FQHC service.)

Telehealth distant-site services - See section 200 of this chapter for additional information on telehealth services in RHCs and FQHCs.

Hospice Services – See section 210 of this chapter for additional information on hospice services in RHCs and FQHCs.

Group Services – Includes group or mass information programs, health education classes, group therapy, or group education activities, including media productions and publications.

70 - RHC and FQHC Payment

(Rev. 252, Issued: 12-07-18, Effective: 01-01-19, Implementation: 01- 02-19)

RHCs and FQHCs must submit claims for RHC or FQHC services under the RHC or FQHC payment methodologies and are not authorized to submit claims under the Physician Fee Schedule (PFS) for RHC or FQHC services. Newly certified RHCs or FQHCs should work with their A/B MAC to ensure that all claims filed for RHC or FQHC services are paid as RHC or FQHC claims as of the date of their certification.

70.1 - RHC Payment

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Medicare pays 80 percent of the RHC AIR, subject to a payment limit, for medically-necessary medical, and qualified preventive, face-to-face (one-on-one) visits with an RHC practitioner (as defined in section 30) for RHC services (as defined in section 50.1), unless otherwise noted. The rate is subject to a payment limit, except for RHCs that have an exception to the payment limit (see section 70.2). An interim rate for newly certified RHCs is established based on the RHC’s anticipated average cost for direct and supporting services. At the end of the reporting period, the A/B MAC determines the

total payment due and reconciles payments made during the period with the total payments due.

In general, the AIR for an RHC is calculated by the A/B MAC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services.

Services furnished incident to an RHC professional service are included in the AIR and are not billed as a separate visit. The professional component of a procedure is usually a covered service, but is not a stand-alone billable visit. The costs of covered services provided incident to a billable visit may be included on the RHC cost report. To receive payment for qualified services, HCPCS coding is required on all claims.

70.2 - RHC Payment Limit and Exceptions

(Rev. 230, Issued: 12-09-16, Effective: 03-09-17, Implementation: 03-09-17)

The RHC payment limit was set by Congress in 1988 and is adjusted annually based on the Medicare Economic Index (MEI). The payment limit is released annually via Recurring Update Notifications.

A provider-based RHC that is an integral and subordinate part of a hospital (including a CAH), as described in regulations at 42 CFR 413.65, can receive an exception to the per-visit payment limit if:

- the hospital has fewer than 50 beds as determined at 42 CFR 412.105(b); or
- the hospital's average daily patient census count of those beds described in 42 CFR 412.105(b) does not exceed 40 and the hospital meets both of the following conditions:
 - it is a sole community hospital as determined in accordance with 42 CFR 412.92 or an essential access community hospital as determined in accordance with 42 CFR 412.109(a), and
 - it is located in a level 9 or level 10 Rural-Urban Commuting Area (RUCA). (For additional information on RUCAs, see <http://depts.washington.edu/uwruca/>.)

The exception to the payment limit applies only during the time that the RHC meets the requirements for the exception.

70.3 - FQHC PPS Payment Rate and Adjustments

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Medicare pays 80 percent of the lesser of the FQHC's charge or the FQHC PPS payment rate for the specific payment code, unless otherwise noted. Except for grandfathered tribal FQHCs, the FQHC PPS payment rate reflects a base rate that is the same for all FQHCs, a geographic adjustment based on the location where services are furnished, and other applicable adjustments as described below. The 2015 and 2016 FQHC PPS base rates were updated by the MEI. Beginning in 2017, the FQHC PPS rate is updated annually by the FQHC market basket. To receive payment for qualified services, HCPCS coding is required on all claims.

Geographic Adjustment: The PPS base rate is adjusted for each FQHC based on its location by the FQHC Geographic Adjustment Factor (FQHC GAF). The PPS payment rate is the PPS base rate multiplied by the FQHC GAF for the location where the service is furnished. Since the FQHC GAF is based on where the services are furnished, the FQHC payment rate may differ among FQHC sites within the same organization. FQHC GAFs are updated periodically and can be found at: <https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html>.

New Patient Adjustment: The PPS payment rate is adjusted by a factor of 1.3416 when an FQHC furnishes care to a patient who is new to the FQHC. A new patient is someone who has not received any Medicare-covered professional health service (medical or mental health) from any site within the FQHC organization, or from any practitioner within the FQHC organization, within the past 3 years from the date of service.

IPPE and AWW Adjustment: The PPS payment rate is adjusted by a factor of 1.3416 when an FQHC furnishes an IPPE or an AWW to a Medicare beneficiary.

NOTE: These adjustments do not apply to grandfathered tribal FQHCs.

70.4 - FQHC Payment Codes

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

FQHCs set their own charges for services they provide and determine which services are included in the bundle of services associated with each FQHC G code based on a typical bundle of services that they would furnish per diem to a Medicare beneficiary. The FQHC should maintain records of the services included in each FQHC G code and the charges associated with the service at the time the service was furnished. Each FQHC decides what documentation is appropriate to record the services included in each G-code pursuant to its own determination. Charges must be reasonable and uniform for all patients, regardless of insurance status. G code services and charges can be changed by the FQHC, but must be the same for all patients and cannot be changed retrospectively.

FQHCs must include one or more of the FQHC payment codes listed below on claims to receive payment for services furnished:

1. G0466 – FQHC visit, new patient: A medically-necessary medical, or a qualified preventive health, face-to-face encounter (one-on-one) between a new patient (as defined

in section 70.3), and an FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving an FQHC visit.

2. G0467 – FQHC visit, established patient: A medically-necessary medical, or a qualifying preventive health, face-to-face encounter (one-on-one) between an established patient and an FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving an FQHC visit.

3. G0468 – FQHC visit, IPPE or AWW: An FQHC visit that includes an IPPE or AWW and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving an IPPE or AWW.

4. G0469– FQHC visit, mental health, new patient: A medically-necessary, face-to-face mental health encounter (one-on-one) between a new patient (as defined in section 70.3), and an FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a mental health visit.

5. G0470 – FQHC visit, mental health, established patient: A medically-necessary, face-to-face mental health encounter (one-on-one) between an established patient and an FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a mental health visit.

80 - RHC and FQHC Cost Reports

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

80.1 - RHC and FQHC Cost Report Requirements

(Rev. 252, Issued: 12- 07-18, Effective: 01-01-19, Implementation: 01- 02-19)

RHCs are required to file a cost report annually in order to determine their payment rate and reconcile interim payments, including adjustments for GME payments, bad debt, and influenza and pneumococcal vaccines and their administration. If in its initial reporting period, the RHC submits a budget that estimates the allowable costs and number of visits expected during the reporting period. The A/B MAC calculates an interim rate based on a percentage of the per-visit limit, which is then adjusted when the cost report is filed.

FQHCs are required to file a cost report annually and are paid for the costs of GME, bad debt, and influenza and pneumococcal vaccines and their administration through the cost report. All FQHCs, including an FQHC that does not have GME costs, bad, debt, or costs associated with influenza and pneumococcal vaccines and their administration, must file a cost report.

RHCs and FQHCs must maintain and provide adequate cost data based on financial and statistical records that can be verified by qualified auditors.

RHCs and FQHCs are allowed to claim bad debts in accordance with 42 CFR 413.89. RHCs may claim unpaid coinsurance and deductible, and FQHCs may claim unpaid coinsurance. RHCs and FQHCs that claim bad debt must establish that reasonable efforts were made to collect these amounts. Coinsurance or deductibles that are waived, either due to a statutory waiver or a sliding fee scale, may not be claimed.

80.2 - RHC and FQHC Consolidated Cost Reports

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

RHCs and FQHCs with more than one site may file consolidated cost reports if approved by the A/B MAC in advance of the reporting period for which the consolidated report is to be used. Once having elected to use a consolidated cost report, the RHC or FQHC may not revert to individual reporting without the prior approval of the A/B MAC.

80.3 – RHC and FQHC Cost Report Forms

(Rev. 230, Issued: 12-09-16, Effective: 03-09-17, Implementation: 03-09-17)

RHCs and FQHCs use one of the following cost report forms:

Independent RHCs and Freestanding FQHCs:

RHCs: Form CMS-222-92, Independent Rural Health Clinic and Freestanding Federally Qualified Health Center Cost Report.

FQHCs: Form CMS-224-14, Federally Qualified Health Center Cost Report.

Provider-based RHCs and FQHCs:

Hospital-based: Worksheet M of Form CMS-2552-10, Hospital and Hospital Care Complex Cost Report.

Skilled Nursing Facility based: Worksheet I series of form CMS-2540-10, “Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report”.

Home Health Agency based: Worksheet RF series of Form CMS-1728-94, “Home Health Agency Cost Report”.

Information on these cost report forms is found in Chapters 29, 44, 32, 40, and 41 and 32, respectively, of the “Provider Reimbursement Manual - Part 2” (Publication 15-2), which can be located on the CMS Website at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html>.

80.4 – RHC Productivity Standards

(Rev.239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Productivity standards are used to help determine the average cost per patient for Medicare reimbursement in RHCs. The current productivity standards require 4,200 visits per full-time equivalent physician and 2,100 visits per full-time equivalent non-physician practitioner (NP, PA, or CNM). Physician and non-physician practitioner productivity may be combined. The FTE on the cost report for providers is the time spent seeing patients or scheduled to see patients and does not include administrative time.

The A/B MAC has the discretion to make an exception to the productivity standards based on individual circumstances. All visits (Medicare, Medicaid, Managed Care, etc.) are included in determining the productivity standards for the cost report.

At the end of the cost reporting year, the A/B MAC re-calculates the AIR by dividing the total allowable costs across all patient types (i.e., the numerator) by the number of visits (as defined in section 40) for all patient types (i.e., the denominator). If fewer than expected visits based on the productivity standards have been furnished, the A/B MAC substitutes the expected number of visits for the denominator and uses that instead of the actual number of visits. The total allowable costs (numerator) would be divided by the higher, expected number of visits (denominator). In this example, this would have the effect of lowering the AIR.

Physician services that are provided on a short term or irregular basis under agreements are not subject to the productivity standards. Instead of the productivity limitation, purchased physician services are subject to a limitation on what Medicare would otherwise pay for the services under the Physician Fee Schedule (PFS), in accordance with 42 CFR 405.2468(d)(2)(v). Practitioners working on a regular, ongoing basis are subject to the productivity standards, regardless of whether they are paid as an employee or independent contractor.

FQHCs are not subject to the productivity standards.

90 - RHC and FQHC Charges, Coinsurance, Deductible, and Waivers

(Rev. 252, Issued: 12-07-18, Effective: 01-01-19, Implementation: 01- 02-19)

Except for certain preventive services for which the coinsurance is statutorily waived, the beneficiary in an RHC must pay the deductible and coinsurance amount, and the beneficiary in an FQHC must pay the coinsurance amount (there is no Part B deductible in FQHCs for FQHC-covered services). For RHCs, the coinsurance is 20 percent of the total charges. For FQHCs, the coinsurance is 20 percent of the lesser of the FQHC's charge for the specific payment code or the PPS rate. For claims with a mix of waived and non-waived services, applicable coinsurance and deductibles are assessed only on the non-waived services. For both RHCs and FQHCs, coinsurance for care management and

virtual communication services is 20 percent of the lesser of submitted charges or the payment rate.

90.1 - Charges and Waivers

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

Charges for services furnished to Medicare beneficiaries must be the same as the charges for non-Medicare beneficiaries. FQHCs may waive collection of all or part of the copayment, depending on the beneficiary's ability to pay. RHCs may waive the copayment and deductible after a good faith determination has been made that the patient is in financial need, provided the waivers are not routine and not advertised. (See 42 U.S.C. 1320a-7a(6)(A))

90.2 - Sliding Fee Scale

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

RHCs may establish a sliding fee scale if it is uniformly applied to all patients. An RHC that chooses to offer a sliding fee scale must post the policy so that all patients are aware of the policy. If the payment policy is based on an individual's income, the RHC must document that income information from the patient was obtained in order to determine that the patient qualified. Copies of their wage statement or income tax return are not required, and self-attestations are acceptable.

FQHCs that are approved by HRSA are required to establish a sliding fee scale in accordance with statutory and HRSA requirements.

100 – Commingling

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Commingling refers to the sharing of RHC or FQHC space, staff (employed or contracted), supplies, equipment, and/or other resources with an onsite Medicare Part B or Medicaid fee-for-service practice operated by the same RHC or FQHC physician(s) and/or non-physician(s) practitioners. Commingling is prohibited in order to prevent:

- Duplicate Medicare or Medicaid reimbursement (including situations where the RHC or FQHC is unable to distinguish its actual costs from those that are reimbursed on a fee-for-service basis), or
- Selectively choosing a higher or lower reimbursement rate for the services.

RHC and FQHC practitioners may not furnish or separately bill for RHC or FQHC-covered professional services as a Part B provider in the RHC or FQHC, or in an area

outside of the certified RHC or FQHC space such as a treatment room adjacent to the RHC or FQHC, during RHC or FQHC hours of operation.

If an RHC or FQHC practitioner furnishes an RHC or FQHC service at the RHC or FQHC during RHC or FQHC hours, the service must be billed as an RHC or FQHC service. The service cannot be carved out of the cost report and billed to Part B.

If an RHC or FQHC is located in the same building with another entity such as an unaffiliated medical practice, x-ray and lab facility, dental clinic, emergency room, etc., the RHC or FQHC space must be clearly defined. If the RHC or FQHC leases space to another entity, all costs associated with the leased space must be carved out of the cost report.

RHCs and FQHCs that share resources (e.g., waiting room, telephones, receptionist, etc.) with another entity must maintain accurate records to assure that all costs claimed for Medicare reimbursement are only for the RHC or FQHC staff, space, or other resources. Any shared staff, space, or other resources must be allocated appropriately between RHC or FQHC and non-RHC or non-FQHC usage to avoid duplicate reimbursement.

This commingling policy does not prohibit a provider-based RHC from sharing its health care practitioners with the hospital emergency department in an emergency, or prohibit an RHC practitioner from providing on-call services for an emergency room, as long as the RHC would continue to meet the RHC conditions for coverage even if the practitioner were absent from the facility. The RHC must be able to allocate appropriately the practitioner's salary between RHC and non-RHC time. It is expected that the sharing of the practitioner with the hospital emergency department would not be a common occurrence.

The A/B MAC has the authority to determine acceptable accounting methods for allocation of costs between the RHC or FQHC and another entity. In some situations, the practitioner's employment agreement will provide a useful tool to help determine appropriate accounting.

110 - Physician Services

(Rev. 252, Issued: 12-07-18, Effective: 01-01-19, Implementation: 01- 02-19)

The term "physician" includes a doctor of medicine, osteopathy, dental surgery, dental medicine, podiatry, optometry, or chiropractic who is licensed and practicing within the licensee's scope of practice, and meets other requirements as specified.

Physician services are professional services furnished by a physician to an RHC or FQHC patient and include diagnosis, therapy, surgery, and consultation. The physician must either examine the patient in person or be able to visualize directly some aspect of

the patient's condition without the interposition of a third person's judgment. Direct visualization includes review of the patient's X-rays, EKGs, tissue samples, etc.

Except for services that meet the criteria for authorized care management or virtual communications services, telephone or electronic communication between a physician and a patient, or between a physician and someone on behalf of a patient, are considered physicians' services and are included in an otherwise billable visit. They do not constitute a separately billable visit.

Qualified services furnished at an RHC or FQHC or other authorized site by an RHC or FQHC physician are payable only to the RHC or FQHC. RHC and FQHC physicians are paid according to their employment agreement or contract (where applicable).

110.1 - Dental, Podiatry, Optometry, and Chiropractic Services (Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Dentists, podiatrists, optometrists, and chiropractors are defined as physicians in Medicare statute, and qualified services furnished by physicians are billable visits in an RHC or FQHC. These practitioners can provide RHC or FQHC services that are within their scope of practice and not excluded from coverage (e.g., Medicare coverage of chiropractic services is limited to manual manipulation of the spine for a demonstrated subluxation).

An RHC or FQHC can bill for a face-to-face, medically necessary visit furnished by a dentist, podiatrist, optometrist, or chiropractor if the service furnished is a qualifying visit for RHCs or FQHCs and all other requirements are met. All services furnished must be within the state scope of practice for the practitioner, and all HCPCS codes must reflect the actual services that were furnished.

RHCs and FQHCs are required to primarily provide primary health care. Since dentists, podiatrists, optometrists, and chiropractors are not considered primary care physicians, they do not meet the requirements to be either i) a physician medical director or ii) the physician or non-physician practitioner (NP, PA, or CNM) that must be available at all times the clinic is open. Therefore, a dentist, podiatrist, optometrist, or chiropractor can provide a medically necessary, face-to-face visit with an RHC or FQHC patient only when the statutory and regulatory staffing requirements are otherwise met.

For additional information on these services, see Pub. 100-02, Medicare Benefit Policy Manual, chapter 15 on Covered Medical and Other Health Service at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

110.2 - Treatment Plans or Home Care Plans (Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Except for comprehensive care plans that are a component of authorized care management services (see section 230), treatment plans and home care oversight provided by RHC or FQHC physicians to RHC or FQHC patients are considered part of the RHC or FQHC visit and are not a separately billable service.

110.3 - Graduate Medical Education

(Rev. 263, Issued: Effective: 01-01-20, Implementation: 01-23-20)

Freestanding RHCs and FQHCs may receive direct graduate medical education (GME) payment for residents if the RHC or FQHC incurs the salaries and fringe benefits (including travel and lodging expenses where applicable) of residents training at the RHC or FQHC. Allowable costs incurred by the RHC or FQHC for GME are paid on a reasonable cost basis and are not subject to the payment limit. RHCs and FQHCs may claim allowable costs only while residents are on their RHC or FQHC rotation.

RHCs and FQHCs that are receiving GME payment may not separately bill for an RHC or FQHC visit provided by a resident, as the cost of these practitioners is included in the GME payment. A medically-necessary medical, or a qualifying preventive health, face-to-face encounter with a teaching physician who is an RHC or FQHC practitioner may be a billable visit if applicable teaching physician supervision and documentation requirements are met.

Under Pub. 100-04, Chapter 12, section 100.1.1.C., the Primary Care Exception (PCE) only applies in an outpatient department or an ambulatory setting where a hospital is claiming on the cost report the residents for indirect medical education and direct GME purposes. Therefore, in the instance where the RHC or FQHC is incurring the cost of the resident(s), the PCE would not apply.

For additional information see 42 CFR 405.2468 (f) and 42 CFR 413.75(b).

120 - Services and Supplies Furnished “Incident to” Physician’s Services

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

“Incident to” refers to services and supplies that are an integral, though incidental, part of the physician’s professional service and are:

- Commonly rendered without charge and included in the RHC or FQHC payment;
- Commonly furnished in an outpatient clinic setting;
- Furnished under the physician’s direct supervision; except for authorized care management services which may be furnished under general supervision; and

- Furnished by RHC or FQHC auxiliary personnel.

Incident to services and supplies include:

- Drugs and biologicals that are not usually self-administered, and Medicare-covered preventive injectable drugs (e.g., influenza, pneumococcal);
- Venipuncture;
- Bandages, gauze, oxygen, and other supplies; or
- Services furnished by auxiliary personnel such as a nurse, medical assistant, or other clinical personnel acting under the supervision of the physician.

Supplies and drugs that must be billed to the DME MAC or to Part D are not included.

NOTE: Payment for Medicare-covered Part B drugs that are not usually self-administered and are furnished by an RHC or FQHC practitioner to a Medicare patient are included in the RHC AIR or the FQHC's PPS per diem payment. However, Section 1861(s)(2)(G) of the Act provides an exception for RHCs when a physician prepares a specific formulation of an antigen for a patient if the antigen is "forwarded to another qualified person (including a rural health clinic) for administration to such patient..., by or under the supervision of another such physician." An RHC practitioner (physician, NP, PA, or CNM) acting within their scope of practice may administer the drug and the cost of the administration may be included on the RHC's cost report as an allowable expense. The cost of the antigen prepared by a physician outside of the RHC is not included in the RHC AIR. Physicians who prepare an antigen that is forwarded to an RHC should submit a claim for the antigen in accordance with instructions from the contractor that processes their Part B claims and applicable CMS requirements.

120.1 - Provision of Incident to Services and Supplies

(Rev. 263, Issued: Effective: 01-01-20, Implementation: 01-23-20)

Incident to services and supplies can be furnished by auxiliary personnel. All services and supplies provided incident to a physician's visit must result from the patient's encounter with the physician and be furnished in a medically appropriate timeframe. More than one incident to service or supply can be provided as a result of a single physician visit.

Incident to services and supplies must be provided by someone who has an employment agreement or a direct contract with the RHC or FQHC to provide services. Services or supplies provided by individuals who are not employed by or under direct contract with the RHC or FQHC, even if provided on the physician's order or included in the RHC or FQHC's bill, are not covered as incident to a physician's service. Services that are not considered incident to include the services of an independently practicing therapist who forwards his/her bill to the RHC or FQHC for inclusion in the entity's statement of services, services provided by an independent laboratory or a hospital outpatient department, services furnished by a nurse, medical assistant, or other auxiliary personnel who is not an employee of or working under contract to the RHC or FQHC, including services provided by a third party under contract, etc.

Services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for authorized care management services (as described in section 230) which may be furnished under general supervision. Direct supervision does not require the physician to be present in the same room. However, the physician must be in the RHC or FQHC and immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished.

When services and supplies are furnished incident to an RHC or FQHC visit, payment for the services are included in the RHC AIR or the FQHC PPS rate. An encounter that includes only an incident to service(s) is not a stand-alone billable visit for RHCs or FQHCs.

120.2 - Incident to Services and Supplies Furnished in the Patient's Home or Location Other than the RHC or FQHC

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Except for authorized care management services, services furnished incident to a physician's visit by RHC or FQHC auxiliary personnel in the patient's home or location other than the RHC or FQHC must have direct supervision by the physician. For example, if an RHC or FQHC nurse accompanies the physician to a patient's home and administers an injection, the nurse's services would be considered incident to the physician's visit. If the same nurse makes the call alone and administers an injection, the services are not incident to services since the physician is not providing direct supervision. The availability of the physician by telephone and the presence of the physician somewhere in the building does not constitute direct supervision. (This rule applies only to the incident to provision. It does not apply to visiting nursing services described in section 190.) For additional information on supervision requirements for Part B services incident to physician services see Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 60.1.

120.3 - Payment for Incident to Services and Supplies

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Services that are covered by Medicare but do not meet the requirements for a medically necessary or qualified preventive health visit with an RHC or FQHC practitioner (e.g., blood pressure checks, allergy injections, prescriptions, nursing services, etc.) are considered incident to services. The cost of providing these services may be included on the cost report, but the provision of these services does not generate a billable visit. Incident to services provided on a different day as the billable visit may be included in the charges for the visit if furnished in a medically appropriate timeframe.

Incidental services or supplies must represent an expense incurred by the RHC or FQHC. For example, if a patient purchases a drug and the physician administers it, the cost of the drug is not covered and cannot be included on the cost report.

If a Medicare-covered Part B drug is furnished by an RHC or FQHC practitioner to a Medicare patient as part of a billable visit, the cost of the drug and its administration is included in the RHC's AIR or the FQHC's PPS payment. RHCs and FQHCs cannot bill separately for Part B drugs or other incident to services or supplies.

130 - Nurse Practitioner, Physician Assistant, and Certified Nurse Midwife Services

(Rev. 252, Issued: 12-07-18, Effective: 01-01-19, Implementation: 01-02-19)

Professional services furnished by an NP, PA, or CNM to an RHC or FQHC patient are services that would be considered covered physician services under Medicare (see section 110), and which are permitted by state laws and RHC or FQHC policies. Services may include diagnosis, treatment, and consultation. The NP, PA, or CNM must directly examine the patient, or directly review the patient's medical information such as X-rays, EKGs and electroencephalograms, tissue samples, etc. Except for services that meet the criteria for authorized care management or virtual communication services, telephone or electronic communication between an NP, PA, or CNM and a patient, or between such practitioner and someone on behalf of a patient, are considered NP, PA, or CNM services, and are included in an otherwise billable visit. They do not constitute a separately billable visit.

130.1 - NP, PA, and CNM Requirements

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

Services performed by NPs, PAs, and CNMs must be:

- Furnished under the general (or direct, if required by state law) medical supervision of a physician;

- Furnished in accordance with RHC or FQHC policies and any physician medical orders for the care and treatment of a patient;
- A type of service which the NP, PA, or CNM who furnished the service is legally permitted to furnish by the state in which the service is rendered;
- Furnished in accordance with state restrictions as to setting and supervision;
- Furnished in accordance with written RHC or FQHC policies that specify what services these practitioners may furnish to patients; and
- A type of service which would be covered under Medicare if furnished by a physician.

130.2 - Physician Supervision

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

RHCs and FQHCs which are not physician-directed must have an arrangement with a physician that provides for the supervision and guidance of NPs, PAs, and CNMs. The arrangement must be consistent with state law.

130.3 - Payment to Physician Assistants

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Section 1842(b)(6)(C) of the Act prohibits PAs from enrolling in and being paid directly for Part B services. The only exception to this is found in Section 4205(d)(3)(B) of the Balanced Budget Act (BBA), which amended Section 1842(b)(6)(C) of the Act to allow Medicare to directly pay a PA when the PA was the owner of an RHC for a continuous period beginning before the date of the enactment of the BBA, and ending on the date the Secretary determines the RHC no longer meets the requirements of Section 1861(aa)(2) of the Act.

140 - Services and Supplies Furnished Incident to NP, PA, and CNM Services

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Services and supplies that are integral, though incident to an NP, PA, or CNM service are:

- Commonly rendered without charge or included in the RHC or FQHC payment
- Commonly furnished in an outpatient clinic setting;

- Furnished under the direct supervision of an NP, PA, or CNM, except for authorized care management services which may be furnished under general supervision; and
- Furnished by a member of the RHC or FQHC staff.

NOTE: The direct supervision requirement is met in the case of an NP, PA, or CNM who supervises the furnishing of the service only if such a person is permitted to exercise such supervision under the written policies governing the RHC or FQHC.

Services and supplies covered under this provision are generally the same as described in section 120 as incident to a physician's services and include services and supplies incident to the services of an NP, PA, or CNM.

150 - Clinical Psychologist (CP) and Clinical Social Worker (CSW) Services

(Rev. 252, Issued: 12- 07-18, Effective: 01-01-19, Implementation: 01- 02-19)

A CP is an individual who:

- Holds a doctoral degree in psychology, and
- Is licensed or certified, on the basis of the doctoral degree in psychology, by the state in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

A CSW is an individual who:

- Possesses a master's or doctor's degree in social work;
- After obtaining the degree, has performed at least 2 years of supervised clinical social work; and
- Is licensed or certified as a clinical social worker by the state in which the services are performed; or, in the case of an individual in a state that does not provide for licensure or certification, meets the requirements listed in 410.73(a)(3)(i) and (ii).

Services may include diagnosis, treatment, and consultation. The CP or CSW must directly examine the patient, or directly review the patient's medical information. Except for services that meet the criteria for authorized care management or virtual communication services, telephone or electronic communication between a CP or CSW and a patient, or between such practitioner and someone on behalf of a patient, are considered CP or CSW services and are included in an otherwise billable visit. They do not constitute a separately billable visit. CSWs are statutorily authorized (1861(hh)(2) of the Act) to furnish services for the diagnosis and treatment of mental illnesses only.

Services that are covered are those that are otherwise covered if furnished by a physician or as incident to a physician's professional service. Services that a hospital or SNF is required to provide to an inpatient or outpatient as a requirement for participation are not included.

Services performed by CPs and CSWs must be:

- Furnished in accordance with RHC or FQHC policies and any physician medical orders for the care and treatment of a patient;
- A type of service which the CP or CSW who furnished the service is legally permitted to furnish by the state in which the service is rendered; and
- Furnished in accordance with state restrictions as to setting and supervision, including any physician supervision requirements.

160 - Services and Supplies Incident to CP and CSW Services

(Rev. 252, Issued: 12-07-18, Effective: 01-01-19, Implementation: 01-02-19)

Services and supplies that are integral, though incident to a CP or CSW service are:

- Commonly rendered without charge or included in the RHC or FQHC payment;
- Commonly furnished in an outpatient clinic setting;
- Furnished under the direct supervision of the CP or CSW, except for authorized care management services which may be furnished under general supervision; and
- Furnished by a member of the RHC or FQHC staff.

NOTE: The direct supervision requirement is met in the case of a CP or CSW who supervises the furnishing of the service only if such a person is permitted to exercise such supervision under the written policies governing the RHC or FQHC. Services and supplies covered under this provision are generally the same as described in section 120 as incident to a physician's services and include services and supplies incident to the services of a CP or CSW.

170 - Mental Health Visits

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

A mental health visit is a medically-necessary face-to-face encounter between an RHC or FQHC patient and an RHC or FQHC practitioner during which time one or more RHC or FQHC mental health services are rendered. Mental health services that qualify as stand-alone billable visits in an FQHC are listed on the FQHC center website, <http://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html>. Services furnished must be within the practitioner's state scope of practice.

Medicare-covered mental health services furnished incident to an RHC or FQHC visit are included in the payment for a medically necessary mental health visit when an RHC or

FQHC practitioner furnishes a mental health visit. Group mental health services do not meet the criteria for a one-one-one, face-to-face encounter in an FQHC or RHC.

A mental health service should be reported using a valid HCPCS code for the service furnished, a mental health revenue code, and for FQHCs, an appropriate FQHC mental health payment code. For detailed information on reporting mental health services and claims processing, see Pub. 100-04, Medicare Claims Processing Manual, chapter 9, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c09.pdf>

Medication management, or a psychotherapy “add on” service, is not a separately billable service in an RHC or FQHC and is included in the payment of an RHC or FQHC medical visit. For example, when a medically-necessary medical visit with an RHC or FQHC practitioner is furnished, and on the same day medication management or a psychotherapy add on service is also furnished by the same or a different RHC or FQHC practitioner, only one payment is made for the qualifying medical services reported with a medical revenue code. For FQHCs, an FQHC mental health payment code is not required for reporting medication management or a psychotherapy add on service furnished on the same day as a medical service.

180 - Physical Therapy, Occupational Therapy, and Speech Language Pathology Services

(Rev. 263, Issued: Effective: 01-01-20, Implementation: 01-23-20)

Physical Therapy (PT), Occupational Therapy (OT), and Speech Language Pathology (SLP) services may be provided in the RHC or FQHC directly by a physician, NP, or PA, if included in the practitioner’s scope of practice. A physician, NP, or PA may also supervise the provision of PT, OT, and SLP services provided incident to their professional services in the RHC or FQHC by a PT, OT, or SLP therapist. PT, OT, and SLP therapists who provide services incident to a physician, NP, or PA visit may be an employee of the RHC or FQHC or contracted to the RHC or FQHC. PT, OT, and SLP services furnished by an RHC or FQHC practitioner or furnished incident to a visit with an RHC or FQHC practitioner are not billable visits.

If the services are furnished on a day when no otherwise billable visit has occurred, the PT, OT, or SLP service provided incident to the visit would become part of the cost of operating the RHC or FQHC. The cost would be included in the costs claimed on the cost report and there would be no billable visit.

190 - Visiting Nursing Services

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

190.1 - Description of Visiting Nursing Services

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

A visiting nurse provides skilled nursing services. The determination of whether a service requires the skills of a nurse is based on the complexity of the service (e.g., intravenous and intramuscular injections or insertion of catheters), the condition of the

patient (e.g., a non-skilled service that, because of the patient's condition, can only be safely and effectively provided by a nurse), and accepted standards of medical and nursing practice. All services must be reasonable and necessary to the diagnosis and treatment of the patient's illness or injury within the context of the patient's unique medical condition.

A service that can be safely and effectively self-administered or performed by a nonmedical person without the direct supervision of a nurse, is not considered a skilled nursing service, even if provided by a nurse.

A service which, by its nature, requires the skills of a nurse to be provided safely and effectively continues to be a skilled service even if it is taught to the patient, the patient's family, or other caregivers. If a patient needs skilled nursing care and there is no one trained or able and willing to provide it, the services of a nurse would be reasonable and necessary to the treatment of the illness or injury.

The determination of whether visiting nurse services are reasonable and necessary is made by the physician based on the condition of the patient when the services were ordered and what is reasonably expected to be appropriate treatment for the illness or injury throughout the certification period.

190.2 - Requirements for Furnishing Visiting Nursing Service (Rev. 252, Issued: 12- 07-18, Effective: 01-01-19, Implementation: 01- 02-19)

RHCs and FQHCs are paid for visiting nursing services when G0490 is on an RHC or FQHC claim and all of the following requirements are met:

- The patient is considered confined to the home as defined in section 1835(a) of the Act and the Medicare Benefit Policy Manual, Chapter 7 (see <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf>;
- The RHC or FQHC is located in an area that has a shortage of home health agencies;
- The services and supplies are provided under a written plan of treatment;
- Nursing services are furnished on a part-time or intermittent basis only; and
- Drugs and biological products are not provided.

190.3 - Home Health Agency Shortage Area (Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

A shortage of HHAs exists if an RHC or FQHC is currently located in a county, parish or similar geographic area in which the Secretary has determined that:

- There is no participating HHA under Medicare, or adequate home health services are not available to RHC or FQHC patients even though a participating HHA is in the area; or
- There are patients whose homes are not within the area serviced by a participating HHA; or considering the area's climate and terrain, whose homes are not within a reasonable traveling distance to a participating HHA.

190.4 - Authorization for Visiting Nursing Services

(Rev. 220, Issued: 01-15-16, Effective: 02-01-16, Implementation: 02-01-16)

RHCs or FQHCs that are located in an area that has not been determined to have a current HHA shortage and are seeking to provide visiting nurse services must make a written request to the CMS RO along with written justification that the area it serves meets the required conditions.

190.5 - Treatment Plans for Visiting Nursing Services

(Rev. 252, Issued: 12- 07-18, Effective: 01-01-19, Implementation: 01- 02-19)

For services and supplies that require a treatment plan, the treatment plan must be written and reviewed by a supervising physician, NP, PA, CNM, or CP, as appropriate, at least once every 60 days; and meet other documentation requirements. If the patient does not receive at least one covered nursing visit in a 60-day period, the plan is considered terminated for the purpose of Medicare coverage unless:

- The supervising physician has reviewed the plan of treatment and made a recertification within the 60-day period which indicates that the lapse of visits is a part of the physician's regimen for the patient, or
- Nursing visits are required at intervals less frequently than once every 60 days, but the intervals are predictable (e.g., it is predictable that a visit is required only every 90 days for the purpose of changing a silicone catheter, etc.).

Home nursing visits furnished before the plan is put into writing are covered if authorized in writing by the supervising physician.

200 - Telehealth Services

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

RHCs and FQHCs may serve as an originating site for telehealth services, which is the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. RHCs and FQHCs that serve as an originating site for telehealth services are paid an originating site facility fee.

Although FQHC services are not subject to the Medicare deductible, the deductible must be applied when an FQHC bills for the telehealth originating site facility fee, since this is not considered an FQHC service.

RHCs and FQHCs are not authorized to serve as a distant site for telehealth consultations, which is the location of the practitioner at the time the telehealth service is furnished, and may not bill or include the cost of a visit on the cost report. This includes telehealth services that are furnished by an RHC or FQHC practitioner who is employed by or under contract with the RHC or FQHC, or a non-RHC or FQHC practitioner furnishing services through a direct or indirect contract. For more information on Medicare telehealth services, see Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, and Pub. 100-04, Medicare Claims Processing Manual, chapter 12.

210 - Hospice Services

(Rev. 230, Issued: 12-09-16, Effective: 03-09-17, Implementation: 03-09-17)

210.1 - Hospice Attending Practitioner

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Medicare beneficiaries who elect the Medicare hospice benefit may choose either an individual physician or NP to serve as their attending practitioner (Section 1861(dd) of the Act). RHCs and FQHCs are not physicians or NPs and are not authorized under the statute to serve in this role. However, a physician or NP who works for an RHC or FQHC may provide hospice attending services during a time when he/she is not working for the RHC or FQHC (unless prohibited by their RHC or FQHC contract or employment agreement). These services would not be considered RHC or FQHC services, since they are not being provided by an RHC or FQHC practitioner during RHC or FQHC hours. The physician or NP would bill for services under regular Part B rules using his/her own provider number. Any service provided to a hospice beneficiary by an RHC or FQHC practitioner must comply with Medicare prohibitions on commingling. (See section 100 of this chapter).

210.2 - Provision of Services to Hospice Patients in an RHC or FQHC

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

RHCs and FQHCs can treat hospice beneficiaries for medical conditions not related to their terminal illness. However, if a Medicare beneficiary who has elected the hospice benefit receives care from an RHC or FQHC related to his/her terminal illness, the RHC or FQHC cannot be reimbursed for the visit, even if it is a medically necessary, face-to-face visit with an RHC or FQHC practitioner, since that would result in duplicate payment for services, except under either of the following circumstances:

- The RHC or FQHC has a contract with the hospice provider to furnish core hospice services related to the patient's terminal illness and related conditions when extraordinary circumstances exist within the hospice. Extraordinary circumstances are described as "unanticipated periods of high patient loads; staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside the hospice's service area" (42CFR 418.64);

- The RHC or FQHC has a contract with the hospice provider to furnish highly specialized nursing services that are provided by the hospice so infrequently that it would be impractical and prohibitively expensive for the hospice to employ a practitioner to provide these services. For example, a hospice may infrequently have a pediatric patient, and in those situations, contract with an RHC or FQHC that has a pediatric nurse on staff to furnish hospice services to the patient.

In these situations, all costs associated with the provision of hospice services must be carved out of the RHC or FQHC cost report, and the RHC or FQHC would be reimbursed by the hospice. (42 CFR 418.64(b)(3)).

Any service provided to a hospice beneficiary by an RHC or FQHC practitioner must comply with Medicare prohibitions on commingling. (See section 100 of this chapter).

220 - Preventive Health Services

(Rev. 230, Issued: 12-09-16, Effective: 03-09-17, Implementation: 03-09-17)

RHCs and FQHCs are paid for the professional component of allowable preventive services when all of the program requirements are met and frequency limits (where applicable) have not been exceeded. The beneficiary copayment and deductible (where applicable) is waived by the Affordable Care Act for the IPPE and AWW, and for Medicare-covered preventive services recommended by the USPSTF with a grade of A or B.

220.1 - Preventive Health Services in RHCs

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Influenza (G0008) and Pneumococcal Vaccines (G0009)

Influenza and pneumococcal vaccines and their administration are paid at 100 percent of reasonable cost through the cost report. No visit is billed, and these costs should not be included on the claim. The beneficiary coinsurance and deductible are waived.

Hepatitis B Vaccine (G0010)

Hepatitis B vaccine and its administration is included in the RHC visit and is not separately billable. The cost of the vaccine and its administration can be included in the line item for the otherwise qualifying visit. A visit cannot be billed if vaccine administration is the only service the RHC provides. The beneficiary coinsurance and deductible are waived.

Initial Preventive Physical Exam (G0402)

The IPPE is a face-to-face one-time exam that must occur within the first 12 months following the beneficiary's enrollment. The IPPE can be billed as a stand-alone visit if it is the only medical service provided on that day with an RHC practitioner. If an IPPE

visit is furnished on the same day as another billable visit, two visits may be billed. The beneficiary coinsurance and deductible are waived.

Annual Wellness Visit (G0438 and G0439)

The AWW is a face-to-face personalized prevention visit for beneficiaries who are not within the first 12 months of their first Part B coverage period and have not received an IPPE or AWW within the past 12 months. The AWW can be billed as a stand-alone visit if it is the only medical service provided on that day with an RHC practitioner. If the AWW is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance and deductible are waived.

Diabetes Self-Management Training (G0108) and Medical Nutrition Therapy (97802 and 97803)

Diabetes self-management training or medical nutrition therapy provided by a registered dietician or nutritional professional at an RHC may be considered incident to a visit with an RHC practitioner provided all applicable conditions are met. DSMT and MNT are not billable visits in an RHC, although the cost may be allowable on the cost report. RHCs cannot bill a visit for services furnished by registered dietitians or nutritional professionals. However, RHCs are permitted to become certified providers of DSMT services and report the cost of such services on their cost report for inclusion in the computation of their AIR. The beneficiary coinsurance and deductible apply.

Screening Pelvic and Clinical Breast Examination (G0101)

Screening pelvic and clinical breast examination can be billed as a stand-alone visit if it is the only medical service provided on that day with an RHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance and deductible are waived.

Screening Papanicolaou Smear (Q0091)

Screening Papanicolaou smear can be billed as a stand-alone visit if it is the only medical service provided on that day with an RHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance and deductible are waived.

Prostate Cancer Screening (G0102)

Prostate cancer screening can be billed as a stand-alone visit if it is the only medical service provided on that day with an RHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance and deductible apply.

Glaucoma Screening (G0117 and G0118)

Glaucoma screening for high risk patients can be billed as a stand-alone visit if it is the only medical service provided on that day with an RHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance and deductible apply.

Lung Cancer Screening Using Low Dose Computed Tomography (LDCT) (G0296)

LDCT can be billed as a stand-alone visit if it is the only medical service provided on that day with an RHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance and deductible are waived.

NOTE: Hepatitis C Screening (G0472) is a technical service only and therefore it is not paid as part of the RHC visit.

220.2 - Copayment and Deductible for RHC Preventive Health Services (Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

When one or more qualified preventive service is provided as part of an RHC visit, charges for these services must be deducted from the total charge for purposes of calculating beneficiary copayment and deductible. For example, if the total charge for the visit is \$150, and \$50 of that is for a qualified preventive service, the beneficiary copayment and deductible is based on \$100 of the total charge, and Medicare would pay 80 percent of the \$100, and 100 percent of the \$50 (minus any deductible). If no other RHC service took place along with the preventive service, there would be no copayment or deductible applied, and Medicare would pay 100 percent of the payment amount.

220.3 - Preventive Health Services in FQHCs

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

FQHCs must provide preventive health services on site or by arrangement with another provider. These services must be furnished by or under the direct supervision of a physician, NP, PA, CNM, CP, or CSW. Section 330(b)(1)(A)(i)(III) of the Public Health Service (PHS) Act required preventive health services can be found at <http://bphc.hrsa.gov/policiesregulations/legislation/index.html>, and include:

- prenatal and perinatal services;
- appropriate cancer screening;
- well-child services;
- immunizations against vaccine-preventable diseases;
- screenings for elevated blood lead levels, communicable diseases, and cholesterol;
- pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care;
- voluntary family planning services; and
- preventive dental services.

NOTE: The cost of providing these services may be included in the FQHC cost report but they do not necessarily qualify as FQHC billable visits or for the waiver of the beneficiary coinsurance.

Influenza (G0008) and Pneumococcal Vaccines (G0009)

Influenza and pneumococcal vaccines and their administration are paid at 100 percent of reasonable cost through the cost report. The cost is included in the cost report and no visit is billed. FQHCs must include these charges on the claim if furnished as part of an encounter. The beneficiary coinsurance is waived.

Hepatitis B Vaccine (G0010)

Hepatitis B vaccine and its administration is included in the FQHC visit and is not separately billable. The cost of the vaccine and its administration can be included in the line item for the otherwise qualifying visit. A visit cannot be billed if vaccine administration is the only service the FQHC provides. The beneficiary coinsurance is waived.

Initial Preventive Physical Exam (G0402)

The IPPE is a face-to-face one-time exam that must occur within the first 12 months following the beneficiary's enrollment. The IPPE can be billed as a stand-alone visit if it is the only medical service provided on that day with an FQHC practitioner. If an IPPE visit is furnished on the same day as another billable visit, FQHCs may not bill for a separate visit. These FQHCs will have an adjustment of 1.3416 to their PPS rate. The beneficiary coinsurance is waived.

Annual Wellness Visit (G0438 and G0439)

The AWV is a personalized face-to-face prevention visit for beneficiaries who are not within the first 12 months of their first Part B coverage period and have not received an IPPE or AWV within the past 12 months. The AWV can be billed as a stand-alone visit if it is the only medical service provided on that day with an FQHC practitioner. If the AWV is furnished on the same day as another medical visit, it is not a separately billable visit. FQHCs that are authorized to bill under the FQHC PPS will have an adjustment of 1.3416 to their PPS rate. The beneficiary coinsurance is waived.

Diabetes Self-Management Training (G0108) and Medical Nutrition Therapy (97802 and 97803)

DSMT and MNT furnished by certified DSMT and MNT providers are billable visits in FQHCs when they are provided in a one-on-one, face-to-face encounter and all program requirements are met. Other diabetes counseling or medical nutrition services provided by a registered dietician at the FQHC may be considered incident to a visit with an FQHC

provider. The beneficiary coinsurance is waived for MNT services and is applicable for DSMT.

DSMT must be furnished by a certified DSMT practitioner, and MNT must be furnished by a registered dietitian or nutrition professional. Program requirements for DSMT services are set forth in 42 CFR 410 Subpart H for DSMT and in Part 410, Subpart G for MNT services, and additional guidance can be found at Pub. 100-02, chapter 15, section 300.

Screening Pelvic and Clinical Breast Examination (G0101)

Screening pelvic and clinical breast examination can be billed as a stand-alone visit if it is the only medical service provided on that day with an FQHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance is waived.

Screening Papanicolaou Smear (Q0091)

Screening Papanicolaou smear can be billed as a stand-alone visit if it is the only medical service provided on that day with an FQHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance is waived.

Prostate Cancer Screening (G0102)

Prostate cancer screening can be billed as a stand-alone visit if it is the only medical service provided on that day with an FQHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance applies.

Glaucoma Screening (G0117 and G0118)

Glaucoma screening for high risk patients can be billed as a stand-alone visit if it is the only medical service provided on that day with an FQHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance applies.

Lung Cancer Screening Using Low Dose Computed Tomography (LDCT) (G0296)

LDCT can be billed as a stand-alone visit if it is the only medical service provided on that day with an FQHC practitioner. If it is furnished on the same day as another medical visit, it is not a separately billable visit. The beneficiary coinsurance is waived.

NOTE: Hepatitis C Screening (G0472) is a technical service only and therefore not paid as part of the FQHC visit.

220.4 - Copayment for FQHC Preventive Health Services

(Rev. 239, Issued: 01-09-18, Effective: 1-22-18, Implementation: 1-22-18)

Under the FQHC PPS, coinsurance will generally be 20 percent of the lesser of the FQHC's charge or the PPS rate. When one or more qualified preventive services are provided as part of an FQHC visit, the A/B MAC will use the lesser of the FQHC's charge for the specific FQHC payment code or the PPS rate to determine the total payment amount. To determine the amount of Medicare payment and the amount of coinsurance that should be waived, the A/B MAC will use the FQHC's reported line-item charges and subtract the dollar value of the FQHC's reported line-item charge for the preventive services from the full payment amount.

For FQHC claims that consist solely of preventive services that are exempt from beneficiary coinsurance, Medicare pays 100 percent of the lesser of the FQHC's charge or the FQHC PPS rate, and no beneficiary coinsurance is assessed.

230 – Care Management Services

(Rev. 10729, Issued: 04-26-21: Effective: 01-01-21, Implementation: 05-26-21)

Care management services are RHC and FQHC service and include transitional care management (TCM), chronic care management (CCM), *principal care management (PCM)*, general behavioral health integration (BHI), and psychiatric collaborative care model (CoCM) services. The RHC and FQHC face-to-face requirements are waived for these care management services. Effective January 1, 2017, care management services furnished by auxiliary personnel may be furnished under general supervision. (Note: General supervision does not require the RHC or FQHC practitioner to be in the same building or immediately available, but it does require the services to be furnished under the overall supervision and control of the RHC or FQHC practitioner.) Except for TCM services, care management services are paid separately from the RHC AIR or FQHC PPS payment methodology. RHCs and FQHCs may not bill for care management services for a beneficiary if another practitioner or facility has already billed for care management services for the same beneficiary during the same time period. RHCs and FQHCs may not bill for care management and TCM services, or another program that provides additional payment for care management services (outside of the RHC AIR or FQHC PPS payment), for the same beneficiary during the same time period. Coinsurance and deductibles are applied as applicable to RHC claims, and coinsurance is applied as applicable to FQHC claims.

230.1 - Transitional Care Management Services

(Rev. 252, Issued: 12-07-18, Effective: 01-01-19, Implementation: 01- 02-19)

Effective January 1, 2013, RHCs and FQHCs are paid for TCM services furnished by an RHC or FQHC practitioner when all TCM requirements are met. TCM services must be furnished within 30 days of the date of the patient's discharge from a hospital (including

outpatient observation or partial hospitalization), SNF, or community mental health center.

Communication (direct contact, telephone, or electronic) with the patient or caregiver must commence within 2 business days of discharge, and a face-to-face visit must occur within 14 days of discharge for moderate complexity decision making (CPT code 99495), or within 7 days of discharge for high complexity decision making (CPT code 99496). The TCM visit is billed on the day that the TCM visit takes place, and only one TCM visit may be paid per beneficiary for services furnished during that 30 day post-discharge period.

TCM services are billed by adding CPT code 99495 or CPT code 99496 to an RHC or FQHC claim, either alone or with other payable services. If it is the only medical service provided on that day with an RHC or FQHC practitioner it is paid as a stand-alone billable visit. If it is furnished on the same day as another visit, only one visit is paid.

230.2 – General Care Management Services – Chronic Care

(Rev. 10729, Issued: 04-26-21; Effective: 01-01-21, Implementation: 05-26-21)

General Care Management Services includes CCM, *PCM* and BHI services. A separately billable initiating visit with an RHC or FQHC primary care practitioner (physician, NP, PA, or CNM) is required before care management services can be furnished. This visit can be an E/M, AWV, or IPPE visit, and must occur no more than one-year prior to commencing care management services. Care management services do not need to have been discussed during the initiating visit, and the same initiating visit can be used for CCM and BHI services as long as it occurs with an RHC or FQHC primary care practitioner within one year of commencement of care management services. Beneficiary consent to receive care management services must be obtained either by or under the direct supervision of the RHC or FQHC primary care practitioner, may be written or verbal and must be documented in the patient's medical record before CCM or BHI services are furnished. The medical record should document that the beneficiary has been informed about the availability of care management services, has given permission to consult with relevant specialists as needed, and has been informed of all of the following:

- There may be cost-sharing (e.g. deductible and coinsurance in RHCs, and coinsurance in FQHCs) for both in-person and non-face-to-face services that are provided;
- Only one practitioner/facility can furnish and be paid for these services during a calendar month; and
- They can stop care management services at any time, effective at the end of the calendar month.

Beneficiary consent remains in effect unless the beneficiary opts out of receiving care management services. If the beneficiary chooses to resume care management services after opting out, beneficiary consent is required before care management services can

resume. If the beneficiary has not opted out of care management services but there has been a period where no care management services were furnished, a new beneficiary consent is not required.

CCM

Effective January 1, 2016, RHCs and FQHCs are paid for CCM services when a minimum of 20 minutes of qualifying CCM services during a calendar month is furnished. CCM services may be furnished to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

CCM service requirements include:

- Structured recording of patient health information using Certified EHR Technology including demographics, problems, medications, and medication allergies that inform the care plan, care coordination, and ongoing clinical care;
- 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week, and continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;
- Comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications;
- Comprehensive care plan including the creation, revision, and/or monitoring of an electronic care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed;
- Care plan information made available electronically (including fax) in a timely manner within and outside the RHC or FQHC as appropriate and a copy of the plan of care given to the patient and/or caregiver;
- Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities; timely creation and exchange/transmit continuity of care document(s) with other practitioners and providers;
- Coordination with home- and community-based clinical service providers, and documentation of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits in the patient's medical record; and

- Enhanced opportunities for the patient and any caregiver to communicate with the practitioner regarding the patient's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods.

PCM

Effective January 1, 2021, RHCs and FQHCs are paid for PCM services when a minimum of 30 minutes of qualifying PCM services are furnished during a calendar month. PCM services may be furnished to patients with a single high-risk or complex condition that is expected to last at least 3 months and may have led to a recent hospitalization, and/or placed the patient at significant risk of death.

PCM service requirements include:

- *A single complex chronic condition lasting at least 3 months, which is the focus of the care plan;*
- *The condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization;*
- *The condition requires development or revision of disease-specific care plan;*
- *The condition requires frequent adjustments in the medication regimen; and*
- *The condition is unusually complex due to comorbidities.*

General BHI

BHI is a team-based, collaborative approach to care that focuses on integrative treatment of patients with primary care and mental or behavioral health conditions. Effective January 1, 2018, RHCs and FQHCs are paid for general BHI services when a minimum of 20 minutes of qualifying general BHI services during a calendar month is furnished to patients with one or more new or pre-existing behavioral health or psychiatric conditions being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC primary care practitioner, warrants BHI services. General BHI service requirements include:

- An initial assessment and ongoing monitoring using validated clinical rating scales;
- Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- Facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and
- Continuity of care with a designated member of the care team.

Payment for General Care Management Services

CCM services furnished between January 1, 2016, and December 31, 2017, are paid based on the PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on an RHC or FQHC claim.

CCM or general BHI services furnished between January 1, 2018, and December 31, 2018, are paid at the average of the national non-facility PFS payment rate for CPT codes 99490 (30 minutes or more of CCM services), 99487 (60 minutes or more of complex CCM services), and 99484 (20 minutes or more of general behavioral health integration services), when general care management HCPCS code G0511 is on an RHC or FQHC claim, either alone or with other payable services.

CCM or general BHI services furnished on or after January 1, 2019, are paid at the average of the national non-facility PFS payment rate for CPT codes 99490, 99487, 99484, and 99491 (30 minutes or more of CCM furnished by a physician or other qualified health care professional), when general care management HCPCS code G0511 is on an RHC or FQHC claim, either alone or with other payable services.

CCM, PCM or general BHI services furnished on or after January 1, 2021 are paid at the average of the national non-facility PFS payment rate for CPT codes 99490, 99487, 99484, and 99491, and HCPCS codes G2064 (30 minutes or more of PCM services furnished by physicians or non-physician practitioners (NPPs)) and G2065 (30 minutes or more of PCM services furnished by clinical staff under the direct supervision of a physician or NPP), when general care management HCPCS code G0511 is on an RHC or FQHC claim, either alone or with other payable services. The payment rate for HCPCS code G0511 is updated annually based on the PFS amounts for these codes.

Coinurance for care management services is 20 percent of lesser of submitted charges or the payment rate for G0511. Care management costs are reported in the non-reimbursable section of the cost report and are not used in determining the RHC AIR or the FQHC PPS rate. G0511 can be billed once per month per beneficiary when at least 20 minutes of CCM services, *at least 30 minutes of PCM services*, or at least 20 minutes of general BHI services have been furnished and all other requirements have been met. Only services furnished by an RHC or FQHC practitioner or auxiliary personnel that are within the scope of service elements can be counted toward the minimum 20 minutes that is required to bill for *CCM and general BHI services and the minimum 30 minutes that is required to bill for PCM services*, and does not include administrative activities such as transcription or translation services.

230.3 – Psychiatric Collaborative Care Model (CoCM) Services (Rev. 263, Issued: Effective: 01-01-20, Implementation: 01-23-20)

Psychiatric CoCM is a specific model of care provided by a primary care team consisting of a primary care provider and a health care manager who work in collaboration with a psychiatric consultant to integrate primary health care services with care management support for patients receiving behavioral health treatment. It includes regular psychiatric inter-specialty consultation with the primary care team, particularly regarding patients

whose conditions are not improving. The primary care team regularly reviews the beneficiary's treatment plan and status with the psychiatric consultant and maintains or adjusts treatment, including referral to behavioral health specialty care, as needed. Patients with mental health, behavioral health, or psychiatric conditions, including substance use disorders, who are being treated by an RHC or FQHC practitioner may be eligible for psychiatric CoCM services, as determined by the RHC or FQHC primary care practitioner. A separately billable initiating visit with an RHC or FQHC primary care practitioner (physician, NP, PA, or CNM) is required before psychiatric CoCM services can be furnished. This visit can be an E/M, AWW, or IPPE visit, and must occur no more than one-year prior to commencing care management services.

Psychiatric CoCM services do not need to have been discussed during the initiating visit, and the same initiating visit can be used for psychiatric CoCM as for CCM and BHI services, as long as it occurs with an RHC or FQHC primary care practitioner within one year of commencement of psychiatric CoCM services. Beneficiary consent to receive care management services must be obtained either by or under the direct supervision of the RHC or FQHC primary care practitioner, may be written or verbal and must be documented in the patient's medical record before psychiatric CoCM services are furnished. The medical record should document that the beneficiary has been informed about the availability of care management services, has given permission to consult with relevant specialists as needed, and has been informed of all of the following:

- There may be cost-sharing (e.g. deductible and coinsurance in RHCs, and coinsurance in FQHCs) for both in-person and non-face-to-face services that are provided;
- Only one practitioner/facility can furnish and be paid for these services during a calendar month; and
- They can stop care management services at any time, effective at the end of the calendar month.

Beneficiary consent remains in effect unless the beneficiary opts out of receiving care management services. If the beneficiary chooses to resume care management services after opting out, beneficiary consent is required before care management services can resume. If the beneficiary has not opted out of care management services but there has been a period where no care management services were furnished, a new beneficiary consent is not required.

RHC or FQHC Practitioner Requirements

The RHC or FQHC practitioner is a primary care physician, NP, PA, or CNM who:

- Directs the behavioral health care manager and any other clinical staff;

- Oversees the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed; and
- Remains involved through ongoing oversight, management, collaboration and reassessment.

Behavioral Health Care Manager Requirements

The behavioral health care manager is a designated individual with formal education or specialized training in behavioral health, including social work, nursing, or psychology, and has a minimum of a bachelor's degree in a behavioral health field (such as in clinical social work or psychology), or is a clinician with behavioral health training, including RNs and LPNs. The behavioral health care manager furnishes both face-to-face and non-face-to-face services under the general supervision of the RHC or FQHC practitioner and may be employed by or working under contract to the RHC or FQHC. The behavioral health care manager:

- Provides assessment and care management services, including the administration of validated rating scales;
- Provides behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- Provides brief psychosocial interventions;
- Maintains ongoing collaboration with the RHC or FQHC practitioner;
- Maintains a registry that tracks patient follow-up and progress;
- Acts in consultation with the psychiatric consultant;
- Is available to provide services face-to-face with the beneficiary; and
- Has a continuous relationship with the patient and a collaborative, integrated relationship with the rest of the care team.

Psychiatric Consultant Requirements

The psychiatric consultant is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant is not required to be on site or to have direct contact with the patient and does not prescribe medications or furnish treatment to the beneficiary directly. The psychiatric consultant:

- Participates in regular reviews of the clinical status of patients receiving psychiatric CoCM services;
- Advises the RHC or FQHC practitioner regarding diagnosis and options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; making adjustments to behavioral health treatment for beneficiaries

who are not progressing; managing any negative interactions between beneficiaries' behavioral health and medical treatments; and

- Facilitates referral for direct provision of psychiatric care when clinically indicated.

Payment for Psychiatric CoCM

Psychiatric CoCM services furnished on or after January 1, 2019, are paid at the average of the national non-facility PFS payment rate for CPT codes 99492 (70 minutes or more of initial psychiatric CoCM services) and CPT code 99493 (60 minutes or more of subsequent psychiatric CoCM services) when psychiatric CoCM HCPCS code, G0512, is on an RHC or FQHC claim, either alone or with other payable services. This rate is updated annually based on the PFS amounts for these codes. At least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months, of psychiatric CoCM services must have been furnished in order to bill for this service.

Coinsurance for psychiatric CoCM services is 20 percent of the lesser of submitted charges or the payment rate for G0512. Psychiatric CoCM costs are reported in the non-reimbursable section of the cost report and are not used in determining the RHC AIR or the FQHC PPS rate. G0512 can be billed once per month per beneficiary when all requirements have been met.

Only services furnished by an RHC or FQHC practitioner or auxiliary personnel that are within the scope of service elements can be counted toward the minimum 60 minutes that is required to bill for psychiatric CoCM services and does not include administrative activities such as transcription or translation services.

240 – Virtual Communication Services

(Rev. 252, Issued: 12-07-18, Effective: 01-01-19, Implementation: 01- 02-19)

Virtual communication services are RHC and FQHC services and include communications-based technology and remote evaluation services. The RHC and FQHC face-to-face requirements are waived when these services are furnished to an RHC or FQHC patient.

Effective January 1, 2019, RHCs and FQHCs receive an additional payment for the costs of communication technology-based services or remote evaluation services that are not already captured in the RHC AIR or the FQHC PPS payment when the requirements for these services are met. Coinsurance and deductibles apply to RHC claims, and coinsurance applies to FQHC claims for these services.

Requirements

The following requirements must be met for RHCs and FQHCs to bill for virtual communication services:

- At least 5 minutes of communications-based technology or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient that has had a billable visit in the RHC or FQHC within the previous year; and
- The medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC service within the next 24 hours or at the soonest available appointment.

If the discussion between the patient and the RHC or FQHC practitioner is related to a billable visit furnished by the RHC or FQHC within the previous 7 days or within the next 24 hours or at the soonest available appointment, the cost of the RHC or FQHC practitioner's time would be included in the RHC AIR or the FQHC PPS payment and is not separately billable.

Payment for Virtual Communication Services

Virtual communication services furnished by RHCs and FQHCs on or after January 1, 2019, are paid at the average of the national non-facility PFS payment rate for HCPCS code G2012 (communication technology-based services), and HCPCS code G2010 (remote evaluation services), when the virtual communication HCPCS code, G0071, is on an RHC or FQHC claim, either alone or with other payable services. The payment rate for HCPCS code G0071 is updated annually based on the PFS amounts for these codes.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R10729BP</u>	04/26/2021	Updates to Medicare Benefit Policy Manual for Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services (Manual Updates Only)	05/26/2021	12252
	12/20/2019	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update	01/23/2020	11575
<u>R252BP</u>	12/07/2018	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update	01/02/2019	11019
<u>R239BP</u>	01/09/2018	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update	01/22/2018	10350
<u>R238BP</u>	11/17/2017	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update	02/15/2018	10350
<u>R230BP</u>	12/09/2016	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Updates	03/09/2016	9864
<u>R220BP</u>	01/15/2016	Rural Health Clinic and Federally Qualified Health Center - Medicare Benefit Policy Manual Update	02/01/2016	9442
<u>R217BP</u>	12/31/2015	Rural Health Clinic and Federally Qualified Health Center - Medicare Benefit Policy Manual Update – Rescinded and replaced by Transmittal 220	02/01/2016	9442
<u>R201BP</u>	12/12/2014	Medicare Benefit Policy Manual - RHC and FQHC Update - Chapter 13	01/05/2015	8981
<u>R173BP</u>	11/22/2013	Medicare Benefit Policy Manual - RHC and FQHC Update - Chapter 13	01/06/2014	8504

<u>R166BP</u>	01/31/2013	Reorganization of Chapter 13	03/01/2013	7824
<u>R114BP</u>	10/30/2009	Outpatient Mental Health Treatment Limitation	01/04/2010	6686
<u>R49BP</u>	03/31/2006	Payment of Federally Qualified Health Centers (FQHCs) for Diabetes Self-Management Training Services (DSMT) and Medical Nutrition Therapy (MNT) Services	06/29/2006	4385
<u>R40BP</u>	11/18/2005	Skilled Nursing Facility Prospective Payment System	02/16/2006	4079
<u>R1BP</u>	10/01/2003	Introduction to the Benefit Policy Manual	N/A	N/A

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Chapter 9 - Rural Health Clinics/ Federally Qualified Health Centers

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10 - Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) General Information

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

10.1 - RHC General Information

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHCs are facilities that provide services that are typically furnished in an outpatient clinic setting. The statutory requirements that RHCs must meet to qualify for the Medicare benefit are in §1861(aa) (2) of the Social Security Act (the Act).

A RHC visit is defined as a medically-necessary, face-to-face (one-on-one) medical or mental health visit, or a qualified preventive health visit, with a RHC practitioner during which time one or more RHC services are rendered. A RHC practitioner is a physician, nurse practitioner (NP), physician assistant (PA), certified nurse midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW). A Transitional Care Management (TCM) service can also be a RHC visit. A RHC visit can also be a visit between a home-bound patient and an RN or LPN under certain conditions.

RHCs can be either independent or provider-based. Independent RHCs are stand-alone or freestanding clinics and submit claims to a Medicare Administrative Contractor (MAC). They are assigned a CMS Certification Number (CCN) in the range of XX3800-XX3974 or XX8900-XX8999. Provider-based RHCs are an integral and subordinate part of a hospital (including a critical access hospital (CAH), skilled nursing facility (SNF), or a home health agency (HHA)).

Information on RHC covered services, visits, payment policies, and other information can be found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 13, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf>.

Information on certification requirements can be found in Pub. 100-07, Medicare State Operations Manual, Chapter 2, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>.

10.2 - FQHC General Information

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

FQHCs are facilities that provide services that are typically furnished in an outpatient clinic setting. FQHC services consist of services that are similar to those furnished in RHCs. The statutory requirements that FQHCs must meet to qualify for the Medicare benefit are in §1861(aa)(4) of the Act. An entity that qualifies as a FQHC is assigned a CCN in the range of XX1000-XX1199 or XX1800-XX1989.

NOTE: Information in this chapter applies to FQHCs that are Health Center Program Grantees and Health Center Program Look-Alikes. It does not necessarily apply to tribal or urban Indian FQHCs or grandfathered tribal (GFT) FQHCs.

20 - RHC and FQHC All-Inclusive Rate (AIR) Payment System (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

20.1 - Per Visit Payment and Exceptions under the AIR (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHCs and FQHCs are paid an AIR per visit, except for FQHCs that have transitioned to the Medicare Prospective Payment System (PPS). For RHCs and FQHCs billing under the AIR, more than one medically-necessary face-to-face visit with a RHC or FQHC practitioner on the same day is payable as one visit, except for the following circumstances:

- The patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day, (for example, a patient sees their practitioner in the morning for a medical condition and later in the day has a fall and returns to the RHC/FQHC);
- The patient has a medical visit and a mental health visit on the same day;
- The patient has an Initial Preventive Physical Examination (IPPE) and a separate qualified medical and/or mental health visit on the same day;
- The patient has a Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) visit on the same day as an otherwise payable medical visit. DSMT and MNT apply to FQHCs only.

20.2 - Payment Limit under the AIR (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

For RHCs and FQHCs that bill under the AIR, Medicare pays 80 percent of the RHC or FQHC's AIR, subject to a payment limit, except for RHCs that have an exception to the payment limit. An interim rate for newly certified RHCs, and for FQHCs certified prior to October, 1, 2014, is established based on the RHC's or FQHC's anticipated average cost for direct and supporting services. At the end of the cost reporting period, the MAC determines the total payment due and reconciles payments made during the period with the total payments due.

For FQHCs paid under the AIR, there is a payment limit for FQHCs located in an urban area and a payment limit for FQHCs located in a rural area. Urban FQHCs are those located within a Metropolitan Statistical Area (MSA). Rural FQHCs cannot be reclassified into an urban area (as determined by the Bureau of Census) for FQHC payment limit purposes. If the FQHC organization includes both urban and rural sites

and the FQHC organization files a consolidated cost report, the FQHC is paid the lower of the FQHC organization's AIR or a single weighted payment limit calculated for the entire FQHC organization. The payment limit is weighted by the percentage of urban and rural visits as a percentage of total visits for the entire FQHC organization.

RHCs and FQHCs paid under the AIR are required to file a cost report annually in order to determine their payment rate. If a RHC or FQHC is in its initial reporting period, the MAC calculates an interim rate based on a percentage of the per-visit limit, which is then adjusted when the cost report is filed.

For information on cost reporting requirements, see the Medicare Provider Reimbursement Manual (PRM), at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html>

30 - FQHC PPS Payment System

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

30.1 - Per-Diem Payment and Exceptions under the PPS

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

Section 10501(i)(3)(A) of the Affordable Care Act (Pub. L. 111-148 and Pub. L. 111-152) added section 1834(o) of the Social Security Act to establish a Medicare PPS for FQHC services. FQHCs transition to the Medicare PPS beginning on October 1, 2014, based on their cost-reporting period. All FQHCs are expected to be transitioned to the PPS by December 31, 2015.

For FQHCs paid under the PPS, Medicare payment is based on the lesser of the FQHC's actual charge or the PPS rate, as determined by the MAC. The FQHC PPS rate will be updated annually beginning January 1, 2016.

For FQHCs billing under the PPS, more than one medically-necessary face-to-face visit with a FQHC practitioner on the same day is payable as one visit, except for the following circumstances:

The patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day, (for example, a patient sees their practitioner in the morning for a medical condition and later in the day has a fall and returns to the FQHC),

The patient has a medical visit and a mental health visit on the same day.

Separate payment is not made to FQHCs under the PPS for an IPPE or DSMT/MNT visit that is furnished on the same day as another FQHC medical visit.

30.2 - Adjustments under the PPS

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

The FQHC PPS rate will be adjusted to account for geographic differences in costs by the FQHC geographic adjustment factor (FQHC GAF). In calculating the PPS rate, the FQHC GAF will be based on the locality of the site where the services are furnished. For FQHC organizations with multiple sites, the FQHC GAF may vary depending on the location of the FQHC delivery site.

The FQHC PPS rate for a covered visit will be calculated as follows:

$$\text{Base payment rate} \times \text{FQHC GAF} = \text{PPS rate}$$

Updates to the FQHC GAFs will be made in conjunction with updates to the Physician Fee Schedule Geographic Practice Cost Indices for the same period and will be posted on CMS's FQHC PPS webpage at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html>.

The PPS per-diem rate will be adjusted by a factor of 1.3416 when a FQHC furnishes care to a patient who is new to the FQHC (has not been a patient at any site that is part of the FQHC organization within the previous 3 years) or to a beneficiary receiving an IPPE or an annual wellness visit (AWV). This is a composite adjustment factor and only one adjustment per day can be applied.

If the patient is new to the FQHC, or the FQHC furnishes an Initial Preventive Physical Examination (IPPE) or Annual Wellness Visit (AWV), the FQHC PPS rate for a covered visit will be calculated as follows:

$$\text{Base payment rate} \times \text{FQHC GAF} \times 1.3416 = \text{PPS rate}$$

For more information on the FQHC PPS, please see the FQHC PPS Final Rule located at: <https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html>

40 - Deductible and Coinsurance

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

40.1 - Part B Deductible

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHC services are subject to an annual deductible of twenty percent of charges for covered services. Effective for dates of service on or after January 1, 2011, the deductible is not applicable for certain preventive services. Please see section 80 for more information on how to bill for preventive services.

RHCs collect the patient's deductible or the portion of the patient's deductible that has not already been met. Once RHCs have billed the MAC for services, they do not collect

or accept any additional money from the patient for their deductible until the MAC notifies the RHC of how much of the deductible has been met.

The Part B deductible does not apply to FQHC services.

40.2 - Part B Coinsurance

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

After any applicable deductibles have been satisfied, RHCs and FQHCs paid under the AIR system will be paid 80 percent of their AIR. The patient is responsible for a coinsurance amount of 20 percent of the charges after deduction of the deductible, where applicable.

Effective for dates of service on or after January 1, 2011, coinsurance is not applicable for certain preventive services. See section 80 of this manual for information on how to bill for preventive services on a RHC and FQHC claims.

FQHCs paid under the PPS will be paid 80 percent of the lesser of the FQHC's actual charge for the specific payment code or the adjusted PPS rate. The patient is responsible for a coinsurance amount of 20 percent of the lesser of the FQHC's actual charge for the specific payment code or the adjusted PPS rate. See section 60.2 for more information on the FQHC specific payment codes.

50 - General Requirements for RHC and FQHC Claims

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 13 for coverage requirements for RHCs and FQHCs. This section addresses requirements for claim submission only.

Section §1862 (a)(22) of the Act requires that all claims for Medicare payment must be submitted in an electronic form specified by the Secretary of Health and Human Services, unless an exception described at §1862 (h) applies. The electronic format required for billing RHC and FQHC services is the ASC X12 837 institutional claim transaction. Instructions relative to the data element names on the Form CMS-1450 hardcopy form are described below. Each data element name is shown in bold type. Information regarding the form locator numbers that correspond to these data element names is found in Chapter 25.

Not all data elements are required or utilized by all payers. Detailed information is given only for items required for Medicare RHC and FQHC claims. Only the items listed below are required for RHCs and FQHCs.

Provider Name, Address, and Telephone Number, Form Locator (FL) 01

The RHC/FQHC enters this information for their agency.

Type of Bill, FL 4

This four-digit alphanumeric code gives three specific pieces of information. The first digit is a leading zero. CMS ignores the first digit. The second digit identifies the type of facility. The third classifies the type of care. The fourth indicates the sequence of this bill in this particular benefit period. It is referred to as a “frequency” code.

Code Structure

1st Digit – Leading Zero
CMS ignores the first digit

2nd Digit - Type of Facility
7 - Special facility (Clinic)

3rdDigit - Classification (Special Facility Only)
1 – Rural Health Clinic
7 – Federally Qualified Health Centers

4th Digit – Frequency	Definition
0 - Nonpayment/Zero Claims	Used when no payment from Medicare is anticipated.
1 - Admit Through Discharge Claim	This code is used for a billing for a confined treatment.
7 - Replacement of Prior Claim	This code is used by the provider when it wants to correct a previously submitted bill. This is the code used on the corrected or “new” bill. For additional information on replacement bills see Chapter 3.
8 - Void/Cancel of a Prior Claim	This code is used to cancel a previously processed claim. For additional information on void/cancel bills see Chapter 3.

Statement Covers Period (From-Through), FL 06

The RHC/FQHC shows the beginning and ending dates of the period covered by this bill in numeric fields (MM-DD-YY).

Patient Name/Identifier, FL 08

The RHC/FQHC enters the beneficiary’s name exactly as it appears on the Medicare card.

Patient Address, FL 09

The RHC/FQHC enters the mailing address of the patient. Enter the complete mailing address.

Patient Birth date, FL10

The RHC/FQHC enters the date of birth of the patient.

Patient Sex, FL 11

The RHC/FQHC enters the sex of the patient as recorded at the start of care.

Priority (Type) of Admission or Visit, FL14

The RHC/FQHC enters the most appropriate NUBC approved code indicating the priority of the visit.

Point of Origin for Admission or Visit, FL 15

The RHC/FQHC enters the most appropriate NUBC approved code indicating the point of origin for this admission or visit.

Patient Discharge Status, FL 16

The RHC/FQHC enters the most appropriate NUBC approved code indicating the patient's status as of the "Through" date of the billing period.

Condition Codes, FL 18-28

The RHC/FQHC enters any appropriate NUBC approved code(s) identifying conditions related to this bill that may affect processing.

Value Codes and Amounts, FL 39-41

The RHC/FQHC enters any appropriate NUBC approved code(s) and the associated value amounts identifying numeric information related to this bill that may affect processing.

Revenue Codes, FL42

The RHC/FQHC assigns a revenue code for each type of service provided and enters the appropriate four-digit numeric revenue code to explain each charge.

For FQHC claims with dates of service on or after January 1, 2010, FQHCs may report additional revenue codes when describing services rendered during an encounter. However, Medicare payment will continue to be reflected only on claim lines with the revenue codes in the following table:

Code	Description
0521	Clinic visit by member to RHC/FQHC
0522	Home visit by RHC/FQHC practitioner
0524	Visit by RHC/FQHC practitioner to a member in a

Code	Description
	covered Part A stay at the SNF
0525	Visit by RHC/FQHC practitioner to a member in a SNF (not in a covered Part A stay) or NF or ICF MR or other residential facility
0527	RHC/FQHC Visiting Nurse Service(s) to a member's home when in a home health shortage area
0528	Visit by RHC/FQHC practitioner to other non RHC/FQHC site (e.g., scene of accident)
0519	Clinic, Other Clinic (only for the FQHC supplemental payment)
0900	Mental Health Treatment/Services

When billing for additional services rendered during the FQHC's encounter, any valid revenue codes may be used with a HCPCS code. However, the following revenue codes are not allowed on FQHC claims:

002x-024x, 029x, 045x, 054x, 056x, 060x, 065x, 067x-072x, 080x-088x, 093x, or 096-310x.

HCPCS/Accommodation Rates/HIPPS Rate Codes, FL 44

For all services provided in a FQHC on or after January 1, 2010 and for approved preventive services provided in a RHC, HCPCS codes are required to be reported on the service lines.

The following HCPCS codes must be reported on FQHC PPS claims:

HCPCS Code	Definition
G0466	FQHC visit, new patient A medically-necessary, face-to-face encounter (one-on-one) between a new patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a FQHC visit.
G0467	FQHC visit, established patient A medically-necessary, face-to-face encounter (one-on-one) between an established patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a FQHC visit.
G0468	FQHC visit, IPPE or AWW

	A FQHC visit that includes an IPPE or AWW and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving an IPPE or AWW.
G0469	FQHC visit, mental health, new patient A medically-necessary, face-to-face mental health encounter (one-on-one) between a new patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a mental health visit.
G0470	FQHC visit, mental health, established patient A medically-necessary, face-to-face mental health encounter (one-on-one) between an established patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a mental health visit.

Modifiers, FL 44

The FQHC reports modifier 59 when billing for a subsequent injury or illness. This is not to be used when a patient sees more than one practitioner on the same day, or has multiple encounters with the same practitioner on the same day, unless the patient, subsequent to the first visit, leaves the FQHC and then suffers an illness or injury that requires additional diagnosis or treatment on the same day.

Modifier 59 is the FQHC's attestation that the patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day. Modifier 59 should only be used when reporting unrelated services that occurred at separate times during the day (e.g., the patient had left the FQHC and returned later in the day for an unscheduled visit for a condition that was not present during the first visit).

For claims subject to the FQHC PPS, modifier 59 is only valid with FQHC Payment Code G0467. Please see section 60.2 of this manual for more information on the FQHC Payment Codes.

Service Date, FL 45

Medicare requires a line item dates of service for all outpatient claims. Medicare classifies RHC/FQHC claims as outpatient claims. Non-payment service revenue codes – report dates as described in the table above under Revenue Codes.

Line items on outpatient claims under HIPAA require reporting of a line-item service date for each iteration of revenue code. A single date must be reported on a line item for the date the service was provided, not a range of dates.

For services that do not qualify as a billable visit, the usual charges for the services are added to those of the qualified visit. RHCs/FQHCs use the date of the visit as the single date on the line item. If there is no billable visit associated with the services, then no claim is filed.

Service Units, FL 46

The RHC/FQHC enters the number of units for each type of service. Units represent visits, which are paid based on the AIR or the FQHC PPS, no matter how many services are delivered. Only one visit is billed per day unless the patient leaves and later returns with a different illness or injury suffered later on the same day.

Total Charges, FL 47

The RHC/FQHC enters the total charge for the service described on each revenue code line.

Payer Name, FL 50

The RHC/FQHC identifies the appropriate payer(s) for the claim.

National Provider Identifier (NPI) – Billing Provider, FL 56

The RHC/FQHC enters its own NPI. When more than one encounter/visits is reported on the same claim i.e., medical and mental health visits, please choose the NPI of the provider that furnished the majority of the services.

Principal Diagnosis Code, FL 67

The RHC/FQHC enters diagnosis coding as required by ICD-9-CM or ICD-10-CM Coding Guidelines.

Other Diagnosis Codes, FL 67A-Q

The RHC/FQHC enters diagnosis coding as required by ICD-9-CM or ICD-10-CM Coding Guidelines.

Attending Provider Name and Identifiers, FL 76

The RHC/FQHC enters the NPI and name of the attending physician designated by the patient as having the most significant role in the determination and delivery of the patient's medical care.

Other Provider Name and Identifiers, FL78-79

The RHC/FQHC enters the NPI and name

NOTE: For electronic claims using version 5010 or later, this information is reported in Loop ID 2310F – Referring Provider Name.

60 - Billing Requirements for RHCs and FQHCs

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHCs and FQHCs are institutional claims and are submitted to the MAC on TOB 71x and 77x. Generally, only those services that are included in the RHC and FQHC benefits are billed on these claims.

- The RHC and FQHC benefits are defined in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 13
(<http://www.cms.hhs.gov/manuals/Downloads/bp102c13.pdf>.)

All professional services in the RHC and FQHC benefit are paid through the AIR system or the FQHC PPS payment for each patient encounter or visit. Technical services (or technical components of services with both professional and technical components) are not billed on RHC/FQHC claims.

For FQHCs with cost reporting periods beginning on or after October 1, 2014, all services are paid according to the FQHC PPS methodology. The visit rate includes: covered services provided by a FQHC practitioner and services and supplies furnished incident to the visit. For additional information on FQHC services, see the Medicare Policy Manual, Chapter 13.

60.1 - Billing Guidelines for RHCs and FQHC Claims under the AIR System

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

When billing Medicare, FQHCs must report all services provided during the encounter/visit by listing the appropriate HCPCS code. The additional revenue lines with detailed HCPCS code(s) are for information and data gathering purposes. RHCs are only required to report the appropriate revenue code for medical and mental health services.

Encounters with more than one health professional and multiple encounters with the same health professionals that take place on the same day and at a single location generally constitute a single visit. For FQHCs, payment is applied to the service line with revenue code 052X and a valid evaluation and management (E&M) HCPCS code for medical visits and revenue code 0900 for mental health visits. Since RHCs are not required to reported detailed HCPCS codes, the payment is applied to the service line with revenue code 052X for medical and revenue code 0900 for mental health visits. However, an additional AIR payment may be made for IPPE, DSMT or MNT (FQHCs only), and a subsequent illness and injuries billed with modifier 59 (FQHCs only).

When reporting multiple services on FQHC claims, the 052X revenue line with the E&M HCPCS code must include the total charges for all of the services provided during the encounter, minus any charges for approved preventive services.

For approved preventive services with a grade of A or B from the United States Preventive Services Task Force (USPSTF), the charges for these services must be deducted from the E&M HCPCS code for the purposes of calculating beneficiary coinsurance correctly. For example, if the total charge for the visit is \$350.00, and

\$50.00 of that is for a qualified preventive service, the beneficiary coinsurance is based on \$300.00 of the total charge.

For Example:

Rev Code	HCPCS code	Modifier	Date of Service	Charges
0521	E&M code*		01/01	300.00
0771	Preventive Service code		01/01	50.00

* RHCs are not required to report a HCPCS code.

Medicare will make an additional AIR payment for IPPE, when billed on the same day with a qualified encounter/visit. When reporting an additional encounter/visit for IPPE, the FQHC or RHC reports the appropriate HCPCS code for the service. The revenue lines should be reflected as follows:

For Example:

Rev Code	HCPCS code	Modifier	Date of Service	Charges
0521	Office Visit		01/01	75.00
0419	Breathing Treatment		01/01	75.00
0521	IPPE		01/01	150.00

For FQHCs, Medicare will make an additional AIR payment for a subsequent illness or injury that occurs on the same day. This is reported on the claim with an additional service line with revenue code 052X, a valid HCPCS code and modifier 59. Please see section 50 for more information on reporting modifier 59.

For Example:

Rev Code	HCPCS code	Modifier	Date of service	Charges
0521	Office Visit		01/01	150.00
0479	Removal of Wax From Ear		01/01	50.00
0521	Office Visit	59	01/01	135.00
0271	Wound Cleaning		01/01	25.00
0279	Bone Setting With Casting		01/01	95.00

Medicare will make an additional AIR payment to FQHCs when DSMT or MNT is reported on the same day with a qualified encounter/visit. When reporting an additional encounter/visit for DSMT or MNT Report the appropriate HCPCS code for the service. The revenue lines should be reflected as follows:

For Example:

Rev Code	HCPCS code	Modifier	Date of Service	Charges
0521	Office Visit		01/01	75.00
0419	Breathing Treatment		01/01	75.00
0521	DSMT or MNT		01/01	150.00

FQHCs must report HCPCS codes for influenza and pneumococcal vaccines and their administration on a FQHC claim, the reporting of these codes are informational only. MACs shall continue to pay for the influenza and pneumococcal vaccines and their administration through the cost report.

60.2 - Billing for FQHC Claims Paid under the PPS (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

FQHCs transitioning to the PPS must submit separate claims for services subject to the PPS and services paid under the AIR.

CMS established five FQHC payment specific codes to be used by FQHCs submitting claims under the PPS. When reporting an encounter/visit for payment, the FQHC must bill on the claim (77X TOB) a FQHC specific payment code.

FQHC Specific Payment Codes

G0466 – FQHC visit, new patient

A medically-necessary, face-to-face encounter (one-on-one) between a new patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a FQHC visit.

G0467 – FQHC visit, established patient

A medically-necessary, face-to-face encounter (one-on-one) between an established patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a FQHC visit.

G0468 – FQHC visit, IPPE or AWV

A FQHC visit that includes an IPPE or AWV and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving an IPPE or AWV.

G0469– FQHC visit, mental health, new patient

A medically-necessary, face-to-face mental health encounter (one-on-one) between a new patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a mental health visit.

G0470 – FQHC visit, mental health, established patient

A medically-necessary, face-to-face mental health encounter (one-on-one) between an established patient and a FQHC practitioner during which time one or more FQHC services are rendered and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving a mental health visit.

FQHCs must use the specific payment code that corresponds to the type of visit that qualifies the encounter for Medicare payment, and these codes will correspond to the appropriate PPS rates. Each FQHC shall report a charge for the FQHC visit code that would reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that would be furnished per diem to a Medicare beneficiary.

FQHC specific payment specific codes G0466, G0467 and G0468 must be reported under revenue code 052X or 0519.

NOTE: Revenue code 0519 is used for Medicare Advantage (MA) Supplemental claims only.

FQHC specific payment codes G0469 and G0470 must be reported under revenue code 0900 or 0519.

FQHCs must report HCPCS coding on the claim to describe all services that occurred during the encounter. All service lines must be reported with their associated charges. The additional services reported on the claim that are part of the FQHC encounter, will not be paid. The payment for these services is included in the payment under the FQHC payment code.

Payment for a FQHC encounter requires a medically necessary face-to-face visit. Each FQHC specific payment code (G0466-G0470) must have a corresponding service line with a HCPCS code that describes the qualifying visit. The link below contains the list of the qualifying visits for each payment specific code:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/Downloads/FQHC-PPS-Specific-Payment-Codes.pdf>

For example:

Revenue Code	HCPCS code	Modifier	Service Date
0521	G0467 – FQHC Payment code		10/01
0521	99213 – Qualifying visit		10/01

When submitting a claim for a mental health visit furnished on the same day as a medical visit, FQHCs must report a specific payment code for a medical visit (G0466, G0467, or G0468) and a specific payment code for a mental health visit (G0470), and each specific payment code must be accompanied by a service line with a qualifying visit.

For example:

Revenue Code	HCPSC code	Modifier	Service Date
0521	G0468 – FQHC Payment code		10/01
0521	G0439 – Qualifying visit		10/01
0900	G0470 – FQHC Payment code		10/01
0900	90832 -Qualifying visit		10/01

When submitting a claim for a subsequent illness or injury, the FQHCs reports G0467 for a medical visit), with modifier 59. A qualifying visit is still required when reporting modifier 59 with G0467.

Revenue Code	HCPSC code	Modifier	Service Date
0521	G0468 – FQHC Payment code		10/01
0521	G0439 – Qualifying visit		10/01
0521	G0467 – FQHC Payment code	59	10/01
0900	99211 -Qualifying visit		10/01

FQHCs must report all services that occurred on the same day on one claim. FQHC may submit claims that span multiple days of service. However, for FQHCs transitioning to the PPS, a separate claim must be submitted for services subject to the PPS and services paid based on the AIR. MACs will reject claims with multiple dates of service that include both PPS and non-PPS dates, as determined based on the individual FQHC's cost reporting period.

FQHCs must report HCPCS codes for influenza and pneumococcal vaccines and their administration on a FQHC claim, and these HCPCS codes will be considered informational only. MACs shall continue to pay for the influenza and pneumococcal vaccines through the cost report.

60.3 - Payments for FQHC PPS Claims

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

Payment for FQHC PPS claims is made by comparing the adjusted FQHC PPS rate to the total submitted covered charges reported for the specific payment codes G0466, G0467, G0468, G0469, and G0470.

To calculate payment, follow the steps below:

Step 1: Determine the lesser of the provider's submitted charges for the specific payment code(s) and the fully-adjusted PPS rate.

Step 2: Determine if preventive services for which the coinsurance is waived are present.

Step 3: Subtract the charges for the preventive services from the lesser of the provider's charge for the specific payment code(s) or the PPS Rate.

(Lesser of the provider's charge for the specific payment code or the PPS rate) - (Preventive services charges) = Step 3 total

Note: If no preventive services are present, use the lesser of the providers charge for the specific payment code(s) or the PPS rate as the Step 3 total.

Step 4: Multiply the total from Step 3 by 80%.

Step 3 total * 80% = Step 4 total

Note: If no preventive services are present, contractors will pay this amount and skip step 5.

Step 5: Add the charges for the approved preventive services to the total from step 4. Contractors will pay this amount.

Step 4 total + preventive services charges = Medicare Payment

Note: If the charges for the approved preventive services are greater than the total payment amount identified in Step 1 (i.e., the lesser of the charges for the specific payment code or the PPS rate), pay 100% of the total payment amount determined in Step 1 and do not apply coinsurance. (Please see example 3)

To calculate coinsurance, follow the steps below:

Step 1: Determine the lesser of the submitted charges for the G-code (s) and the PPS rate.

Step 2: Determine if approved preventive services (i.e., preventive services for which coinsurance is waived) are present.

Step 3: Subtract the charges for the preventive services from the lesser of the provider's charge for the specific payment code(s) or the PPS Rate.

(Lesser of the provider's charge for the specific payment code or the PPS rate) - (Preventive services charges) = Step 3 total

Note: If no approved preventive services are present, use the lesser the provider's charge for the specific payment code(s) or the PPS rate as the Step 3 total.

Step 4: Multiply the total from Step 3 by 20%.

Step 3 total * 20% = Coinsurance

- Example: Payment based on the charges**

PPS rate = 160.00

Provider's actual charge for the specific payment code, G0467 = \$150

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0467		10/01	150.00	150.00
0521	99213		10/01	135.00	135.00
0300	36415		10/01	25.00	25.00
0001				310.00	310.00

The comparison is between the PPS rate and the provider's \$150 actual charge for the specific payment code, G0467. In this case, the sum of the line items exceeds the provider's actual charge for the payment code.

Payment based on the provider's charge of 150.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Coinsurance
0521	G0467		10/01	150.00	150.00	120.00	30.00
0521	99213		10/01	135.00	135.00	CO 97*	0
0300	36415		10/01	25.00	25.00	CO 97	0
0001				310.00	310.00		

Payment = 150.00 (charges) * 80%

Coinsurance = 150.00 (charges) * 20%

For service lines that do not receive payment, group code CO- contractual obligation and the appropriate claim adjustment reason code (CARC) will be used.

* CARC 97 – the benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated.

- Example: Payment based on the charges with approved preventive service**

PPS rate = 160.00

Provider's actual charge for the specific payment code, G0468 = \$150

Preventive Service = 135.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0468		10/01	150.00	150.00
0521	G0439 PS**		10/01	135.00	135.00
0300	36415		10/01	25.00	25.00
0001				310.00	310.00

Payment based on the provider's actual charge of 150.00 for the specific payment code, G0468.

REV CODE	HCPC CODE	MOD S	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Co-insurance
0521	G0468		10/01	150.00	150.00	147.00	3.00
0521	G0439 PS		10/01	135.00	135.00	CO 97*	0
0300	36415		10/01	25.00	25.00	CO 97	0
0001				310.00	310.00		

Payment = (150.00 (charges) – 135.00 (preventive service G0439)) * 80% + 135.00 preventive service

Coinsurance = (150.00 (charges) – 135.00 (preventive service G0439)) * 20%

- ** PS – Preventive Service -These are approved preventive services where the coinsurance is waived based on the USPSTF recommendation.

Example: Payment based on the charges when preventive service is greater than G-code

PPS rate = 160.00

Provider's actual charge for the specific payment code, G0468 = \$150 Preventive Service = 155.00

REV CODE	HCPC	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0468		10/01	150.00	150.00
0521	G0439 PS		10/01	155.00	155.00
0300	36415		10/01	25.00	25.00
0001				330.00	330.00

Payment based on charges of 150.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Co-insurance
0521	G0468		10/01	150.00	150.00	150.00	0
0521	G0439 PS		10/01	155.00	155.00	CO 97*	0
0300	36415		10/01	25.00	25.00	CO 97	0
0001				330.00	330.00		

Payment = (150.00 (charges) * 100% = 150.00

Since the charges for the preventive service, G0439 are greater than the provider's actual charge for the specific payment code G0468, Medicare pays 100% of the provider's actual charge for the specific payment code, G0468.

Reporting Multiple G-codes

When a FQHC reports multiple specific payment codes (G-codes) on the same day, the total payment amount will be determined by comparing the sum of the charges for all the G-codes reported to the PPS rate. When a qualified mental health visit occurs on the same day as a qualified medical visit, the G-codes will be totaled separately (see example 8).

Listed below is the order in which payment will be applied when multiple G-codes are reported on the same day:

Medical visits:

- G0468-IPPE or AWW
- G0466-Medical, new patient
- G0467-Established patient

Mental health visits:

- G0469-Mental health, new patient
- G0470- Mental health, established patient

When G0466 (Medical, new patient) and G0468 (IPPE or AWW) are reported together, the add-on payment will be applied to G0468.

• **Example: Payment based on PPS rate with multiple G-codes and preventive services**

Because this scenario does not qualify for an exception to a per diem payment, the system will calculate and apply a PPS rate to only one of the specific payment codes. However, the FQHC may list its actual charges for both specific payment codes, and the comparison would be between the PPS rate and the total of the provider's charges for the specific payment codes. Payment would be based on the lesser amount.

PPS RATE, reflecting a 1.3416 adjustment for new patients or a visit including an IPPE or AWW = 215.00

Total of provider charges for the specific payment codes (170.00 + 65.00) = 235.00

Provider's charge for the Preventive Service = 135.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0468		10/01	170.00	170.00
0521	G0438 PS		10/01	135.00	135.00
0300	36415		10/01	25.00	25.00
0521	G0466		10/01	65.00	65.00
0521	92004		10/01	45.00	45.00
0001				440.00	440.00

Payment based on adjusted PPS rate of 215.00

REV CODE	HCPC CODE	MOD S	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Coinsurance
0521	G0468		10/01	170.00	170.00	199.00	16.00
0521	G0438 PS		10/01	135.00	135.00	CO 97	0
0300	36415		10/01	25.00	25.00	CO 97	0
0521	G0466		10/01	65.00	65.00	CO 97	0
0521	92004		10/01	45.00	45.00	CO 97	0
0001				440.00	440.00		

Payment = (215.00 (PPS rate) – 135.00 (preventive service G0438) * 80% + 135.00 preventive service

Coinsurance = (215.00 (PPS rate) – 135.00 (preventive service G0438)) * 20%

Reporting Multiple Preventive Services

When multiple preventive services are reported on the same day, the coinsurance will be determined by carving out the total preventive services charges.

- **Example: Payment based on PPS rate with multiple G-codes and multiple preventive services**

PPS RATE = 225.00

Total G code charges (140.00 + 75.00 + 55.00) = 270.00

Total Preventive Services (135.00 + 60.00) = 195.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0468		10/01	140.00	140.00
0521	G0439 PS		10/01	135.00	135.00
0300	36415		10/01	25.00	25.00
0521	G0467		10/01	75.00	75.00
0521	97802 PS		10/01	60.00	60.00
0521	G0466		10/01	55.00	55.00
0521	92004		10/01	45.00	45.00
0001				535.00	535.00

Payment based on PPS rate of 225.00

REV CODE	HCPC CODE	MOD S	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Co-insurance
0521	G0468		10/01	140.00	140.00	219.00	6.00
0521	G0439 PS		10/01	135.00	135.00	CO 97	0
0300	36415		10/01	25.00	25.00	CO 97	0
0521	G0467		10/01	75.00	75.00	CO 97	0

0521	97802 PS		10/01	60.00	60.00	CO 97	0
0521	G0466		10/01	55.00	55.00	CO 97	0
0521	92004		10/01	45.00	45.00	CO 97	0
0001				535.00	535.00		

Payment = $(225.00 - (135.00 + 60.00)) * 80\% + 135.00 + 60.00$

Coinsurance = $(225.00 \text{ (PPS rate)} - (135.00 + 60.00)) * 20\%$

Influenza and Pneumococcal Pneumonia Vaccination (PPV)

Flu and PPV vaccines and their administration will continue to be paid through the cost report. However, these services should be reported on the claim for information purposes only. Flu and PPV vaccines and their administration codes will not be carved out of the coinsurance calculation.

- **Example: Payment based on charges with Flu and Flu administration code services**

PPS rate = 160.00

Preventive Service = 135.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0468		10/01	150.00	150.00
0521	G0438 PS		10/01	135.00	135.00
0636	90655		10/01	15.00	15.00
771	G0008		10/01	5.00	5.00
0001				305.00	305.00

Payment based on charges of 150.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Co-insurance
0521	G0468		10/01	150.00	150.00	150.00	0
0521	G0438 PS		10/01	135.00	135.00	CO 97	0
0636	90655 ****		10/01	15.00	15.00	CO 246***	0
0771	G0008 ****		10/01	5.00	5.00	CO 246	0
0001				305.00	305.00		

Because flu and PPV are reported on the claim for information purposes only, G0438 remains as the only service payable on this claim. Because the claim consists solely of preventive services for which coinsurance is waived, the contractor will pay 100% of the provider's actual charge for the specific payment code, G0468.

*** CARC 246- This non-payable code is for required reporting only.

**** Flu/PPV are reported on the claim for information purposes only, the payment and coinsurance are not impacted by the charges associated with the Flu/PPV vaccine and their administration code.

Hepatitis B

Hepatitis B should be reported on the claim and is included in the claim payment. These services will be carved out of the coinsurance calculation.

- **Example: Payment based on charges with Hepatitis B**

PPS rate= 160.00

Preventive Services = 20.00 (15.00 +5.00)

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0467		10/01	150.00	150.00
0521	99213		10/01	135.00	135.00
0300	36415		10/01	5.00	5.00
0636	90746 PS		10/01	15.00	15.00
771	G0010 PS		10/01	5.00	5.00
0001				310.00	310.00

Payment based on charges of 150.00

REV CODE	HCPC CODE	MOD S	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Co-insurance
0521	G0467		10/01	150.00	150.00	124.00	26.00
0521	99213		10/01	135.00	135.00	CO 97	0
0300	36415		10/01	5.00	5.00	CO 97	0
0636	90746 PS		10/01	15.00	15.00	CO 97	0
0771	G0010 PS		10/01	5.00	5.00	CO 97	0
0001				310.00	310.00		

Payment = (150.00 (charges) – 20.00 (preventive service 90746 + G0010)) * 80% + 20.00 preventive

Coinsurance = (150.00 (charges) – 20.00 (preventive service 90746 + G0010)) * 20%

Mental Health Services

Qualified mental health visits billed under revenue code 0900 receive an additional payment when billed on the same day as a medical visit.

- **Example: Mental Health Services**

PPS RATE for G0468: \$225.00

PPS rate for G0470: \$160

Total of provider's actual charges for the specific payment codes representing medical visits (140.00 + 75.00 + 55.00) = 270.00- This does not include charges for G0470

Provider's charge for the specific payment code representing mental health services = 159.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0468		10/01	140.00	140.00
0521	G0439 PS		10/01	135.00	135.00
0300	36415		10/01	25.00	25.00
0521	G0467		10/01	75.00	75.00
0521	97802 PS		10/01	60.00	60.00
0521	G0466		10/01	55.00	55.00
0521	92004		10/01	45.00	45.00
0900	G0470		10/01	159.00	159.00
0900	90832		10/01	139.00	139.00
0636	J3490		10/01	15.00	15.00
0001				848.00	848.00

Payment based on PPS rate of 225.00 for the specific payment codes describing the medical visits and based on the provider's actual charges for the specific payment code describing the mental health visit.

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Co-insurance
0521	G0468		10/01	140.00	140.00	219.00	6.00
0521	G0439 PS		10/01	135.00	135.00	CO 97	0
0300	36415		10/01	25.00	25.00	CO 97	0
0521	G0467		10/01	75.00	75.00	CO 97	0
0521	97802 PS		10/01	60.00	60.00	CO 97	0
0521	G0466		10/01	55.00	55.00	CO 97	0
0521	92004		10/01	45.00	45.00	CO 97	0
0900	G0470		10/01	159.00	159.00	127.20	31.80
0900	90832		10/01	139.00	139.00	CO 97	0
0636	J3490		10/01	15.00	15.00	CO 97	0
0001				848.00	848.00		

For Medical visit with revenue code 052X

Payment = (225.00 – (135.00 + 60.00)) * 80% + 135.00 + 60.00

Coinurance = (225.00 (PPS rate) – (135.00 + 60.00)) * 20%

For Mental Health visit with revenue code 0900

Payment = 159.00 * 80% = 127.20

Coinsurance = $159.00 \times 20\% = 31.80$

Modifier 59

Medicare allows for an additional payment when an illness or injury occurs subsequent to the initial visit, and the FQHC bills these visits with the specific payment codes and modifier 59. Services billed with a modifier 59 will be paid an additional per diem rate

- **Example: Modifier 59**

PPS rate for G0468 = 225.00

Total G code charges ($140.00 + 75.00 + 55.00$) = 270.00 – This does not include charges for G0470 and G-code charges for modifier 59

Total mental Health Services = 159.00

PPS rate for G0467 (billed with Modifier 59) = 160.00

REV CODE	HCPC CODE	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0521	G0468		10/01	140.00	140.00
0521	G0438 PS		10/01	135.00	135.00
0300	36415		10/01	25.00	25.00
0521	G0467		10/01	75.00	75.00
0521	97802 PS		10/01	60.00	60.00
0521	G0466		10/01	55.00	55.00
0521	92004		10/01	45.00	45.00
0900	G0470		10/01	159.00	159.00
0900	90832		10/01	139.00	139.00
0636	J3490		10/01	15.00	15.00
0521	G0467	59	10/01	165.00	165.00
0521	99211		10/01	105.00	105.00
0001				1118.00	1118.00

Payment based on PPS rate of 225.00 for the G-codes, based on the charges for the mental health visit and based on the PPS rate for G0467 billed with modifier 59.

REV CODE	HCPC CODE	MOD S	SERV DATE	TOTAL CHARGE	COV CHARGE	Payment	Coinsurance
0521	G0468		10/01	140.00	140.00	219.00	6.00
0521	G0438 PS		10/01	135.00	135.00	CO 97	0
0300	36415		10/01	25.00	25.00	CO 97	0
0521	G0467		10/01	75.00	75.00	CO 97	0
0521	97802 PS		10/01	60.00	60.00	CO 97	0
0521	G0466		10/01	55.00	55.00	CO 97	0
0521	92004		10/01	45.00	45.00	CO 97	0

0900	G0470		10/01	159.00	159.00	127.20	31.80
0900	90832		10/01	139.00	139.00	CO 97	0
0636	J3490		10/01	15.00	15.00	CO 97	0
0521	G0467	59	10/01	165.00	165.00	128.00	32.00
0521	99211		10/01	105.00	105.00	CO 97	0
0001				1118.00	1118.00		

For Medical visit with revenue code 052X

Payment = $(225.00 - (135.00 + 60.00)) * 80\% + 135.00 + 60.00$

Coinurance = $(225.00 \text{ (PPS rate)} - (135.00 + 60.00)) * 20\%$

For Mental Health visit with revenue code 0900

Payment = $159.00 * 80\% = 127.20$

Coinurance = $159.00 * 20\% = 31.80$

For G0467 billed with modifier 59

Payment = $160.00 * 80\% = 128.00$

Coinurance = $160.00 * 20\% = 32.00$

60.4 - Billing for Supplemental Payments to FQHCs under Contract with Medicare Advantage (MA) Plans

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

Section 237 of the Medicare Modernization Act (MMA) requires CMS to provide supplemental payments to FQHCs that contract with MA organizations to cover the difference, if any, between the payment received by the FQHC for treating MA enrollees and the payment to which the FQHC would be entitled to receive under the cost-based all-inclusive payment rate as set forth in 42 CFR, Part 405, Subpart X.

This supplemental payment for covered FQHC services furnished to MA enrollees augments the direct payments made by the MA organization to FQHCs for all covered FQHC services. The Medicare per diem payment, which continues to be made for all covered FQHC services furnished to Medicare beneficiaries participating in the original Medicare program, is based on the FQHC's unique cost-per-visit as calculated by the MAC. The MAC determines if the Medicare payments that the FQHC would be entitled to exceed the amount of payments received by the FQHC from the MA organization and, if so, pay the difference to the FQHC.

FQHCs seeking the supplemental payment are required to submit (for the first two rate years) to the MAC an estimate of the average MA payments (per visit basis) for covered FQHC services. They are required to submit a documented estimate of their average per visit payment for their MA enrollees, for each MA plan they contract with, and any other information as may be required to enable the MAC to accurately establish an interim supplemental payment.

Expected payments from the MA organization would only be used until actual MA revenue and visits collected on the FQHC's cost report can be used to establish the amount of the supplemental payment.

Effective January 1, 2006, eligible FQHCs will report actual MA revenue and visits on their cost reports. At the end of each cost reporting period the MAC shall use actual MA revenue and visit data along with the FQHC's final all-inclusive payment rate, to determine the FQHC's final actual supplemental per visit payment. Once this amount (per visit basis) is determined it will serve as the interim rate for the next full rate year. Actual aggregated supplemental payments will then be reconciled with aggregated interim supplemental payments, and any underpayment or overpayment thereon will then be accounted for in determining final Medicare FQHC program liability at cost settlement.

An FQHC is only eligible to receive this supplemental payment when FQHC services are provided during a face-to-face encounter between an MA enrollee and one or more of the following FQHC covered core practitioners: physicians, nurse practitioners, physician assistants, certified nurse midwives, clinical psychologists, or clinical social workers. The supplemental payment is made directly to each qualified FQHC through the MAC.

Each FQHC seeking the supplemental payment is responsible for submitting a claim for each qualifying visit to the MAC on type of bill (TOB) 77x with revenue code 0519 for the amount of the interim supplemental payment rate (FQHC interim all-inclusive rate – estimated average payment from the MA plan plus any beneficiary cost sharing = billed amount > 0). Do not submit revenue codes 052X and/or 0900 on the same claim as revenue code 0519.

For services of plan years beginning on and after January 1, 2006 and before, an interim supplemental rate can be determined by the MAC based on cost report data, MACs shall calculate an interim supplemental payment for each MA plan the FQHC has contracted with using the documented estimate provided by the FQHC of their average MA payment (per visit basis) under each MA plan they contract with. Once an interim supplemental rate is determined for a previous plan year based on cost report data, use that interim rate until the MAC receives information that changes in service patterns that will result in a different interim rate. MACs shall calculate an interim supplemental payment rate for each MA plan the FQHC has contracted with. Reconcile all interim payments at cost settlement.

Do not apply the Medicare deductible when calculating the FQHC interim supplemental payment. Do not apply the original Medicare co-insurance (20%) to the FQHC all inclusive rate when calculating the FQHC interim supplemental payment. Any beneficiary cost sharing under the MA plan is included in the calculation of the FQHC interim supplemental payment rate.

MACs shall submit all claims to CWF for approval. CWF will verify each beneficiary's enrollment in an MA plan for the line item date of service (LIDOS) on the claim. CWF

shall reject all claims for the FQHC interim supplemental payment for beneficiaries who are not MA enrollees on the same date as the LIDOS on the claim. MACs shall RTP such claims to the FQHCs. MACs shall accept TOB 77x with revenue code 0519 and pay the interim supplemental payment rate for each qualified visit billed.

Billing for Supplemental Payments under the AIR

When billing for supplemental payment to the MAC, the encounter is reported on type of bill (TOB) 77x with revenue code 0519 for the amount of the interim supplemental payment rate (FQHC interim all-inclusive rate – estimated average payment from the MA plan plus any beneficiary cost sharing = billed amount > 0). Do not submit revenue codes 0520 and/or 0900 on the same claim as revenue code 0519. HCPCS coding is not required.

For Example:

Rev Code	HCPCS code	Modifier	Date of Service	Charges
0519	blank		01/01	150.00

Billing for Supplemental Payments under the PPS

When billing for supplemental payment to the MAC under the PPS, a FQHC payment specific code and a qualifying visit must be reported under revenue code 0519.

For example:

Revenue Code	HCPCS code	Modifier	Service Date
0519	G0467 – FQHC Payment code		10/01
0519	99213 – Qualifying visit		10/01

60.5 - PPS Payments to FQHCs under Contract with MA Plans (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

For claims with the 0519 revenue code, the wraparound payment is based on the PPS rate without comparison to the provider's charge. The rate is also NOT adjusted for coinsurance or preventive services as the MA plan would have already assessed any applicable coinsurance and related waivers of coinsurance.

Medicare will compare the PPS rate with the MA contract rate for a FQHC visit.

When the MA contract rate is lower than the applicable PPS rate that would otherwise have been paid by traditional Medicare had the beneficiary not been covered by the MA plan, the contractor will pay the difference as a supplemental wraparound payment.

The FQHC does not qualify for a supplemental wraparound payment when the MA contract rate is higher than the applicable PPS rate that would otherwise have been paid by traditional Medicare had the beneficiary not be covered by the MA plan.

- **Example: MA Claim that Qualifies for a Supplemental Wraparound Payment**

PPS Rate = \$225

Rev	HCPC	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0519	G0468		10/01	170.00	170.00
0519	G0439 PS		10/01	150.00	150.00
0001				320.00	320.00

If the MA contract rate is lower than the applicable PPS rate – e.g., \$200:

Wraparound payment = PPS rate – MA contract rate = \$225 - \$200 = \$25

Note that the charge of \$170 would reflect the FQHC's typical charge for G0468, but would not be used to calculate the supplemental payment.

- **Example : MA Claim that Does Not Qualify for a Supplemental Wraparound Payment**

PPS Rate = \$225

Rev	HCPC	MODS	SERV DATE	TOTAL CHARGE	COV CHARGE
0519	G0468		10/01	170.00	170.00
0519	G0439 PS		10/01	150.00	150.00
0001				320.00	320.00

If the MA contract rate was higher than the applicable PPS rate – e.g., the MA contract rate was \$250- no wraparound payment is due to the FQHC.

60.6 - RHCs and FQHCs for billing Hospice Attending Physician Services (Rev. 11200, Issued :01-12-22, Effective: 01-01-22, Implementation: 01-03-22)

Effective for services furnished on or after January 1, 2022, RHCs or FQHCs can bill and receive payment under the RHC All-Inclusive Rate (AIR) or FQHC Prospective Payment System (PPS), when a designated attending physician employed by or working under contract with the RHC or FQHC furnishes hospice attending physician services during a patient's hospice election.

RHCs must report a GV modifier on the claim line for payment (that is, along with the CG modifier) each day a hospice attending physician service is furnished.

FQHCs must report a GV modifier on the claim line with the payment code (G0466 – G0470) each day a hospice attending physician service is furnished.

The hospice attending physician services are subject to coinsurance and deductibles on RHC claims and only coinsurance on FQHC claims.

70 - General Billing Requirements for Preventive Services

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

Professional components of preventive services are covered under the RHC and FQHC benefit. The payment for most preventive services is included with a qualified visit as part of the overall encounter/visit. To ensure coinsurance and deductible (deductible applies to RHC claims only) are applied correctly, detailed HCPCS coding is required for approved preventive services recommended by the USPSTF with a grade of A or B for TOBs 71x or 77x. Additionally, RHCs/FQHCs are required to report HCPCS codes for certain preventive services subject to frequency limits.

70.1 - RHCs Billing Approved Preventive Services

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

An additional line with the appropriate site of service revenue code in the 052X series should be submitted with the approved preventive service HCPCS code and the associated charges. For example, if the total charge for the visit is \$150.00, and \$50.00 of that is a qualified preventive service, the service lines should be coded as follows:

Revenue Code	HCPCS code	Modifier	Service Date	Charges
0521	Encounter = Blank or valid HCPCS code		10/01	100.00
0521	Preventive Service Code		10/01	50.00

In the example above, the encounter service line will receive the AIR payment. The charges reported on this line should not include the charges for the approved preventive service. Coinsurance and deductible will be accessed based on the charges reported on this service line. The qualified preventive service reported on the additional service line will not receive payment, as payment is made under the AIR for the services reported under the encounter service line. Coinsurance and deductible are accessed based on the charges reported on the preventive services line.

70.2 - FQHCs Billing Approved Preventive Services under the AIR

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

Detailed HCPCS codes are required for all service lines. When reporting the encounter/visit, revenue code 052X for medical and revenue code 0900 for mental health visits must be used. For additional services, the most appropriate revenue code for the service rendered should be used.

Revenue Code	HCPCS code	Modifier	Service Date	Charges
0521	Encounter = E&M HCPCS code		10/01	100.00
0771	Preventive Service Code		10/01	50.00

In the example above, the services reported under the encounter/visit service line will receive the AIR payment. The charges reported on this line should not include the charges for the approved preventive service. Since deductible does not apply to FQHC claims, only coinsurance will be applied to the charges reported on the encounter service line. The qualified preventive service reported on the second revenue line will not receive payment. Coinsurance and deductible are not accessed to the services reported under the preventive services line.

70.3 - FQHC Billing Approved Preventive Services under the PPS (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

An additional line with the appropriate site of service revenue code in the 052X series should be submitted with the approved preventive service HCPCS code and the associated charges. For example, if the total charge for the visit is \$150.00, report the total charges for the encounter. **NOTE:** Do not carve out the charges for the approved preventive services. The service lines should be coded as follows:

Revenue Code	HCPCS code	Modifier	Service Date	Charges
0521	Encounter = FQHC Payment Code (G-code) code		10/01	150.00
0771	Preventive Service code		10/01	75.00

In the example above, the services reported under the encounter/visit service line will receive the PPS payment. The charges reported on this line **should** include the charges for the approved preventive service. The coinsurance will be applied to the charges reported on the encounter service line. Coinsurance will not be applied to the charges reported for the approved preventive service. The qualified preventive service reported on the second revenue line will not receive payment. **NOTE:** A qualified HCPCS code visit must be reported if the preventive service is not a qualified visit.

70.4 - Vaccines (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHCs do not report charges for influenza virus or pneumococcal pneumonia vaccines on the 71x claim. However, FQHCs must report these services with their charges on the 77x claim for informational and data collection purposes only.

The costs for the influenza virus or pneumococcal pneumonia vaccines for RHCs and FQHCs are included in the cost report. Neither coinsurance nor deductible apply to either of these vaccines.

Hepatitis B vaccine is included in the encounter rate. The charges of the vaccine and its administration can be included in the line item for the otherwise qualifying encounter. An encounter cannot be billed if vaccine administration is the only service the RHC/FQHC provides.

Additional information on vaccines can be found in Chapter 1, section 10 of this manual. Additional coverage requirements for pneumococcal vaccine, hepatitis B vaccine, and influenza virus vaccine can be found in Publication 100-02, the Medicare Benefit Policy Manual, Chapter 13.

70.5 - Diabetes Self Management Training (DSMT) and Medical Nutrition Services (MNT)

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

FQHCs billing under the AIR system

Payment is made at the all-inclusive encounter rate to the FQHC for DSMT or MNT. This payment can be in addition to payment for another qualifying visit on the same date of service as the beneficiary received qualifying DSMT services.

For FQHCs to qualify for a separate visit payment for DSMT or MNT services, the services must be a one-on-one face-to-face encounter. Group sessions do not constitute a billable visit for any FQHC services. To receive separate payment for DSMT or MNT services, the services must be billed on TOB 77x with HCPCS code G0108 (DSMT) or HCPCS code 97802, 97803, or G0270 (MNT) and the appropriate site of service revenue code in the 052X revenue code series. This payment can be in addition to payment for any other qualifying visit on the same date of service that the beneficiary received qualifying DSMT /MNT services as long as the claim for DSMT/MNT services contains the appropriate coding specified above. Additional information on DSMT can be found in Chapter 18, section 120 of Pub. 100-04.

Additional information on MNT can be found in Chapter 4, section 300 of Pub. 100-04.

Group services (G0109, 97804 and G0271) do not meet the criteria for a separate qualifying encounter. All line items billed on TOBs 77x with group services will be denied.

DSMT and MNT services are subject to the frequency edits described in Pub. 100-04, Chapter 18, and should not be reported on the same day.

FQHCs billing under the PPS

DSMT and MNT are qualifying visits when billed under G0466 or G0467. For additional information on the payment specific codes and qualifying visits, see section 60.2 of this manual. Under the FQHC PPS, DSMT and MNT do not qualify for a separate payment when billed on the same day with another qualified visit.

RHCs

RHCs are not paid separately for DSMT and MNT services. All line items billed on TOB 71x with HCPCS codes for DSMT and MNT services will be denied.

70.6 - Initial Preventive Physical Examination (IPPE)

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

FQHCs and RHCs billing under the AIR system

Medicare provides for coverage for one IPPE for new beneficiaries only, subject to certain eligibility and other limitations.

Payment for the professional services will be made under the AIR. However, RHCs/FQHCs can receive a separate payment for an encounter in addition to the payment for the IPPE when they are performed on the same day.

When IPPE is provided in an RHC or FQHC, the professional portion of the service is billed on TOBs 71X and 77X, respectively, and the appropriate site of service revenue code in the 052X revenue code series, and must include HCPCS code G0402. Additional information on IPPE can be found in Chapter 18, section 80 of Pub. 100-04.

EKGs

The professional component is included in the AIR or FQHC PPS and is not separately billable.

The technical component of an EKG performed at a RHC/FQHC billed to Medicare on professional claims (Form CMS-1500 or 837P) under the practitioner's ID following instructions for submitting practitioner claims for independent/freestanding clinics. Practitioners at provider-based clinics bill the applicable TOB to the A/B MAC using the base provider's ID.

FQHCs billing under the PPS:

IPPE is qualifying visits when billed under G0468, for additional information on the payment specific codes and qualifying visits, please refer to section 60.2 of this manual. Under the FQHC PPS, IPPE does not qualify for a separate payment when billed on the same day with another encounter/visit.

70.7 - Virtual Communication Services

(Rev. 10357, Issued: 09-18-2020, Effective: 10-19-2020, Implementation: 10-19-2020)

In the CY 2019 PFS final rule, CMS finalized a policy for payment to RHCs and FQHCs for communication technology-based services (“virtual check-in”) or remote evaluation services, effective January 1, 2019. CMS created a new Virtual Communications G Code, G0071 for use by RHCs and FQHCs only, with the payment rate set at the average of the PFS non-facility payment rate for communication technology-based services and remote evaluation services.

RHCs and FQHCs receive an additional payment for the costs of communication technology-based services or remote evaluation services that are not already captured in the RHC AIR or the FQHC PPS payment when the requirements for these services are met. Coinsurance and deductibles apply to RHC claims, and coinsurance applies to FQHC claims for these services.

RHCs and FQHCs can bill HCPCS code G0071 alone or with other payable services on an RHC or FQHC claim. The services should be billed with a revenue code 052x and should not be billed with modifier CG for payment on RHC claims. HCPCS codes G0071 are paid based on the lesser of the charges or the rate from the Medicare Physician Fee Schedule (MPFS).

70.8- General Care Management Services – Chronic Care or Psychiatric Collaborative Care Model (CoCM) Services

(Rev. 10357, Issued: 09-18-2020, Effective: 10-19-2020, Implementation: 10-19-2020)

Effective for services furnished on or after January 1, 2018, RHCs and FQHCs are paid for General Care Management or Psychiatric CoCM services when G0511 or G0512 is billed alone or with other payable services on an RHC or FQHC claim. HCPCS code G0511 or G0512 can only be billed once per month per beneficiary, and cannot be billed if other care management services are billed for the same time period.

HCPCS codes G0511 and G0512 are subject to coinsurance and deductibles on RHC claims. Only coinsurance applies on FQHC claims. Coinsurance is 20 percent of the lesser of the RHC or FQHC’s charge for HCPCS codes G0511 and G0512, or the corresponding rate.

The allowable revenue code is 052X. These HCPCS codes of G0511 or G0512 should not be billed with modifier CG for payment on RHC claims.

80 - Telehealth Services

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHCs and FQHCs may bill the Telehealth originating site facility fee on a RHC or FQHC claim under revenue code 0780 and HCPCS code Q3014. Telehealth services are the only services billed on FQHC claims that are subject to the Part B deductible. Additionally, a FQHC payment code and qualifying visit HCPCS code are not required when the only service reported on the claim is for Telehealth services. RHCs and FQHCs are not authorized to serve as distant practitioners for Telehealth services.

For more information on Telehealth services please see Pub 100-04, chapter 12, section 190: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>

90 - Services non-Covered on RHC and FQHC Claims (Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

Technical Services

RHCs/FQHCs do not bill using TOBs 71x or 77x for technical components of services because they are not within the scope of Medicare-covered RHC/FQHC services. The associated technical components of services furnished by the RHC/FQHC are billed on other types of claims that are subject to applicable frequency limits edits.

For services that can be split into professional and technical components, RHCs and FQHCs bill for the professional component as part of the AIR or the FQHC PPS payment and bill the MAC separately for the technical component. See Chapter 17, section 30.1.1, for more information on how RHCs and FQHCs can bill the MAC for laboratory services. See Chapter 13 for more information on how to bill the MAC for technical components of diagnostic services.

- Technical services/components associated with professional services/components performed by independent RHCs or FQHCs are submitted to the MAC in the designated claim format (837P or Form CMS-1500.) See chapters 12 (<http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf>) and 26 (<http://www.cms.hhs.gov/manuals/downloads/clm104c26.pdf>) of this manual for billing instructions.
- Technical services/components associated with professional services/components performed by provider-based RHCs or FQHCs are submitted by the base-provider on the appropriate TOB to the MAC in the designated claim format (837I or the UB-04 claim form); see the applicable chapter of this manual based on the base-provider type, such as (<http://www.cms.hhs.gov/manuals/downloads/clm104c04.pdf>) for outpatient hospital services, chapter 6 (<http://www.cms.hhs.gov/manuals/downloads/clm104c06.pdf>) for inpatient SNF services chapter 7 for Outpatient SNF services, etc.

Laboratory Services

RHCs must furnish the following lab services to be approved as an RHC. However, these and other lab services that may be furnished are not included in the encounter rate and must be billed separately.

- Chemical examinations of urine by stick or tablet method or both;
- Hemoglobin or hematocrit;
- Blood sugar;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory (No CPT code available).

RHCs/FQHCs bill all laboratory services to their MAC under the host provider's bill type and payment is made under the fee schedule. HCPCS codes are required for lab services.

Venipuncture is included in the AIR and the PPS per diem payment and is not separately billable.

Refer to Chapter 16 for general billing instructions.

Durable Medical Equipment (DME), ambulance services, hospital-based services, group services, and non-face-to-face services are also non-covered and are billed separately.

When billing these services on FQHC PPS claims, a FQHC payment code and qualifying visit HCPCS code is **not** required.

100 - Frequency of Billing and Same Day Billing

(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHC and FQHC claims cannot overlap calendar years. Therefore, the statement dates, or from and through dates of the claim, must always be in the same calendar year.

RHCs and FQHCs billing under the FQHC PPS may submit claims that span multiple days of service.

FQHCs billing under the PPS must submit all services that are rendered on the same day on one claim.

General information on basic Medicare claims processing can be found in this manual in:

Chapter 1, “General Billing Requirements,”
(<http://www.cms.hhs.gov/manuals/downloads/clm104c01.pdf>) for general claims processing information;

Chapter 2, “Admission and Registration Requirements,”
(<http://www.cms.hhs.gov/manuals/downloads/clm104c02.pdf>) for general filing requirements applicable to all providers.

For Medicare institutional claims:

See the Medicare Claims Processing Manual on the CMS website for general Medicare institutional claims processing requirements, such as for timely filing and payment, admission processing, and Medicare Summary Notices.

Contact your MAC for basic training and orientation material if needed.

Version 03/15/2022
Check for Updates

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R11200CP</u>	01/12/2022	Implementation of the GV Modifier for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for Billing Hospice Attending Physician Services	01/03/2022	12357
<u>R11095CP</u>	10/29/2021	Implementation of the GV Modifier for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for Billing Hospice Attending Physician Services - Rescinded and replaced by Transmittal 11200	01/03/2022	12357
<u>R11029CP</u>	09/29/2021	Implementation of the GV Modifier for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for Billing Hospice Attending Physician Services - Rescinded and replaced by Transmittal 11095	01/03/2022	12357
<u>R10907CP</u>	08/10/2021	Implementation of the GV Modifier for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for Billing Hospice Attending Physician Services - Rescinded and replaced by Transmittal 11029	01/03/2022	12357
<u>R10357CP</u>	09/18/2020	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 9, Section 70.7 and 70.8.	10/19/2020	11961
<u>R3434CP</u>	12/31/2015	Reorganization of Chapter 9	03/31/2016	9397
<u>R3000CP</u>	07/25/2014	Update to Pub. 100-04, Chapter 09 to Provide Language-Only Changes for Updating ASC X12	08/25/2014	8670
<u>R2186CP</u>	03/28/2011	Waiver of Coinsurance and Deductible for Preventive Services in Rural Health Clinics (RHCs), Section 4104 of Affordable Care Act (ACA)	04/04/2011	7208
<u>R2122CP</u>	12/21/2010	Waiver of Coinsurance and Deductible for	04/04/2011	7208

Preventive Services in Rural Health
Clinics (RHCs), Section 4104 of
Affordable Care Act (ACA) – Rescinded
and replaced by Transmittal 2186

<u>R2093CP</u>	11/12/2010	Waiver of Coinsurance and Deductible for Preventive Services in Rural Health Clinics (RHCs), Section 4104 of Affordable Care Act (ACA) – Rescinded and replaced by Transmittal 2122	04/04/2011	7208
<u>R2034CP</u>	08/24/2010	Affordable Care Act (ACA) Mandated Collection of Federally Qualified Health Center (FQHC) Data and Updates to Preventive Services Provided by FQHCs	01/03/2011	7038
<u>R2013CP</u>	07/30/2010	Affordable Care Act (ACA) Mandated Collection of Federally Qualified Health Center (FQHC) Data and Updates to Preventive Services Provided by FQHCs - Rescinded and replaced by Transmittal 2034	01/03/2011	7038
<u>R1843CP</u>	10/30/2009	Outpatient Mental Health Treatment Limitation	01/04/2010	6686
<u>R1719CP</u>	04/24/2009	Rural Health Clinic (RHC) and Federally Qualified Health Clinic (FQHC) Updates	10/05/2009	6445
<u>R1707CP</u>	03/27/2009	Assignment of Initial Enrollment FQHC'S, ESRD Facilities, and RHC's	04/27/2009	6207
<u>R1472CP</u>	03/06/2008	Update of Institutional Claims References	04/07/2008	5893
<u>R1426CP</u>	02/01/2008	Announcement of Medicare Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Payment Rate Increases	02/12/2008	5896
<u>R1421CP</u>	01/25/2008	Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472	04/07/2008	5893
<u>R1255CP</u>	05/25/2007	Guidelines for Payment of Diabetes Self-Management Training DSMT)	07/02/2007	5433
<u>R1158CP</u>	01/19/2007	Guidelines for Payment of Diabetes Self-Management Training DSMT) – Replaced	07/02/2007	5433

by Transmittal 1255

<u>R820CP</u>	02/01/2006	Sites of Service Revenue Codes for Rural Health Clinics and Federally Qualified Health Centers	07/03/2006	4210
<u>R794CP</u>	12/29/2005	Announcement of Medicare Supplemental Payments to Federally Qualified Health Centers Under Contract with Medicare Advantage Plan	04/03/2006	3886
<u>R773CP</u>	12/02/2005	Announcement of the Medicare Federally Qualified Health Center Supplemental Payment	04/03/2006	3886
<u>R771CP</u>	12/02/2005	Revisions to Pub. 100-04, Medicare Claims in Preparation for the National Provider Identifier (NPI)	01/03/2006	4181
<u>R371CP</u>	11/19/2004	Updated Billing Instructions for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)	04/04/2005	3487
<u>R167CP</u>	04/30/2004	Discontinued Use of Revenue Code 0910	10/04/2004	3194
<u>R001CP</u>	10/01/2003	Initial Publication of Manual	NA	NA

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Attachment - One-Time Notification

Pub. 100-20	Transmittal: 1637	Date: March 23, 2016	Change Request: 9269
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Transmittal 1596, dated January 26, 2016 is being rescinded and replaced by Transmittal 1637 to add FISS to business requirement 9269.1. All other information remains the same.

SUBJECT: Required Billing Updates for Rural Health Clinics

EFFECTIVE DATE: April 1, 2016

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: April 4, 2016

I. GENERAL INFORMATION

A. Background: For dates of service on or after April 1, 2005 through December 31, 2010, Rural Health Clinics (RHCs) billing under the all-inclusive rate (AIR) were not required to report HCPCS coding when billing for RHC services, absent a few exceptions. Generally, it has not been necessary to require reporting of HCPCS since the AIR system was designed to provide payment for all of the costs associated with an encounter for a single day.

Provisions of the Affordable Care Act of 2010 further modified the billing requirements for RHCs. Effective January 1, 2011, Section 4104 of the Affordable Care Act, waived the coinsurance and deductible for the initial preventive physical examination (IPPE), the annual wellness visit (AWV), and other Medicare covered preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. In accordance with policy, RHCs have been required to report HCPCS codes when furnishing certain preventive services since January 1, 2011.

CMS regulations require covered entities to report standard medical code sets for electronic health care transactions, although CMS program instructions have directed RHCs to submit HCPCS codes only for preventive services. Such standard medical code sets are defined as level I and level II of the HCPCS. In the CY 2016 PFS proposed rule (80 FR 41943), CMS proposed that all RHCs, including RHCs exempt from electronic reporting under §424.32(d)(3), are required to submit HCPCS and other codes as required on claims for services furnished. The requirements for RHCs to submit HCPCS codes were finalized in the CY 2016 PFS final rule with comment period (80 FR 71088).

B. Policy: Effective for dates of service on or after April 1, 2016, RHCs, including RHCs exempt from electronic reporting under §424.32(d)(3), are required to report the appropriate HCPCS code for each service line along with the revenue code, and other codes as required.

Payment for RHC services will continue to be made under the AIR when all of the program requirements are met. There is no change in the AIR system and payment methodology including the “carve out” methodology for coinsurance calculation due to this reporting requirement.

Basic Guidelines on RHC Visits and Billing for 71X Types of Bills (TOBs):

An RHC visit is defined as a medically necessary medical or mental health visit, or a qualified preventive health visit. The visit must be a face-to-face (one-on-one) encounter between the patient and an RHC practitioner during which time one or more RHC services are furnished. A Transitional Care Management (TCM) service can also be an RHC visit. Qualified preventive health services include the initial preventive physical examination (IPPE), the annual wellness visit (AWV), and other Medicare covered preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. Additional information on what constitutes a RHC visit can be found in the Medicare Benefit Policy

manual, Pub 100-02, Chapter 13.

Beginning with dates of service on or after April 1, 2016, when billing Medicare, RHCs are required to report the appropriate HCPCS code for each line item along with revenue code.

RHC qualifying visits are typically evaluation and management (E/M) type of services or screenings for certain preventive services. See Attachment A for a list of HCPCS codes that are defined as qualifying visits, which corresponds with the following guidance on service level information.

Service Level Information:

- The professional component of qualified medical services are reported on a line item using revenue 052X (free-standing clinic).
- When an approved preventive health service is furnished, report it on an additional 052X service line.
- Mental health services are reported on a line item using revenue code 0900 (mental health treatment services).

RHCs shall report one service line per encounter/visit with revenue code 052X and a medical service qualifying visit from Attachment A. Payment will be applied to the service line with revenue code 052X and a valid medical service qualifying visit, and coinsurance and/or deductible will be applied to this line. When a preventive health service is reported on an additional 052X line it is not eligible for a separate per diem payment, except for the initial preventive physical exam (IPPE).

When a preventive health service is the only qualifying visit reported for the encounter, payment will be applied to this service line with revenue code 052X. For approved preventive services, frequency edits apply and coinsurance and/or deductible will be waived for the line.

RHCs shall report one service line per mental health encounter/visit with revenue code 0900 and a mental health service qualifying visit from Attachment A.

Billing for Exceptions to the Same Day Policy:

Encounters with more than one RHC practitioner on the same day, or multiple encounters with the same RHC practitioner on the same day, constitute a single RHC visit and is payable as one visit. Except for the following circumstances:

- The patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day, (for example, a patient sees their practitioner in the morning for a medical condition and later in the day has a fall and returns to the RHC). The subsequent medical service should be billed using a valid HCPCS code, revenue code 052X, and modifier 59. Modifier 59 signifies that the conditions being treated are totally unrelated and services are provided at separate times of the day.
- The patient has a medical visit and a mental health visit on the same day.
- The patient has an IPPE and a separate medical and/or mental health visit on the same day. IPPE is a once in a lifetime benefit and should be billed using HCPCS code G0402 and revenue code 052X. For IPPE, the beneficiary coinsurance and deductible are waived.

Please refer to Attachment A for a list of HCPCS codes that are defined as qualifying visits.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility							
		A/B MAC		D M E	Shared- System Maintainers				Other
		A	B		F I S S	M C S	V M S	C W F	
9269.1	Contractors shall allow RHCs to report all valid revenue codes except the following: 002x-024x, 029x, 045x, 054x, 056x, 060x, 065x, 067x-072x, 080x-088x, 093x, or 096x-310x	X				X			
9269.2	Contractors shall require all service lines reported on RHC claims (TOB 71X) to contain a valid HCPCS code except for revenue codes that do not require HCPCS code reporting, i.e. revenue code 025x.	X							
9269.2.1	Contractors shall return to the provider all RHC claims with service lines that do not contain a valid HCPCS code except for revenue codes that do not require HCPCS code reporting, i.e. revenue code 025x.	X							
9269.3	Contractors shall only allow RHCs to report one service line per day with revenue code 052X and a qualifying visit HCPCS code (attachment A) for medical services. This does not apply to approved preventive health services listed in attachment A and services reported with modifier 59.					X			
9269.3.1	Contractors shall only allow RHCs to report one service line per day with revenue code 0900 and a qualifying visit HCPCS code (attachment A) for mental health services.					X			
9269.3.2	Contractors shall return to the provider all RHC claims that contain more than one qualifying visit HCPCS code from attachment A billed under revenue code 052X for medical service lines (excluding approved preventive services and modifier 59) and mental health services billed under revenue code 0900.	X							
9269.4	Contractors shall make an AIR payment for each of the following on RHC claims per day: <ul style="list-style-type: none"> Medical services with revenue code 052X and a qualifying visit HCPCS code from Attachment A (this applies to non-preventive and preventive services); 					X			

Number	Requirement	Responsibility								Other
		A/B MAC			D M E M A C	Shared- System Maintainers				
		A	B	H H H		F I S S	M C S	V M S	C W F	
	<ul style="list-style-type: none">Mental health services with revenue code 0900 and a qualifying visit HCPCS code from Attachment A;IPPE, HCPCS code G0402 with revenue code 052X (<i>subject to CWF frequency edits</i>);Medical services with revenue code 052X, a qualifying visit HCPCS code from Attachment A and modifier 59. <p>NOTE: When a qualifying visit HCPCS code for a medical service is reported on the same day with a qualifying visit HCPCS code for preventive health, pay the medical service visit at the AIR, (excluding IPPE, G0402) and package/bundle the preventive health service line (9269.6). When a qualifying visit HCPCS code for an approved preventive service (from attachment A) is billed on the same day with a qualifying visit HCPCS code for a mental health service, both services should be paid based on AIR.</p>									
9269.4.1	Contractors shall apply coinsurance and deductible based on submitted charges to service lines paid at the AIR. NOTE: This does not apply to approved preventive services where coinsurance and/or deductible is waived.					X				
9269.5	Contractors shall continue to pay for Telehealth services with revenue code 0780 and HCPCS code Q3014 based on the lesser of the actual charges or the fee amount. Telehealth services do not have to be reported with an encounter/visit. NOTE: Deductible and coinsurance apply.					X				
9269.6	Contractors shall ensure any service lines not receiving the AIR payment on RHC claims are shown as covered with the following ANSI information: Group code CO- Contractual obligation CARC 97 The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Note: Refer to the					X				

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared- System Maintainers			Other	
		A	B	H H H		F I S S	M C S	V M S		C W F
	835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. RARC M15 Separately billed services/tests have been bundled as they are considered components of the same procedure. Separate payment is not allowed. MSN 16.34 - You should not be billed for this service. You are only responsible for any deductible and coinsurance amounts listed in the ‘You May Be Billed’ column.									
9269.7	Contractors shall ensure RHC claims with preventive service HCPCS codes are posted to the appropriate auxiliary files as a professional component.								X	
9269.8	Contractors shall apply the appropriate frequency edits to RHC claims for preventive services.								X	
9269.9	The IOCE shall assign edit 91 to reject service lines containing DME (revenue code 029X), Lab (excluding 36415), Ambulance (revenue code 054X), Hospital-Based Care (99217-99239, 99281-99292, and 99460-99480), Group (97804, G0271) and non-Face-to-Face (99441-99444) services on RHC claims.					X				IOCE

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
9269.10	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next	X				

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
	regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Tracey Mackey, 410-786-5736 or tracey.mackey@cms.hhs.gov , Simone Dennis, 410-786-8409 or Simone.Dennis@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Attachment A-
RHC Qualifying Visits

Medical Services

HCPCS Code	Short Descriptor
92002	Eye exam new patient
92004	Eye exam new patient
92012	Eye exam establish patient
92014	Eye exam&tx estab pt 1/>vst
99201	Office/outpatient visit new
99202	Office/outpatient visit new
99203	Office/outpatient visit new
99204	Office/outpatient visit new
99205	Office/outpatient visit new
99212	Office/outpatient visit est
99213	Office/outpatient visit est
99214	Office/outpatient visit est
99215	Office/outpatient visit est
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99307	Nursing fac care subseq
99308	Nursing fac care subseq
99309	Nursing fac care subseq
99310	Nursing fac care subseq
99315	Nursing fac discharge day
99316	Nursing fac discharge day
99318	Annual nursing fac assessmnt
99324	Domicil/r-home visit new pat
99325	Domicil/r-home visit new pat
99326	Domicil/r-home visit new pat
99327	Domicil/r-home visit new pat
99328	Domicil/r-home visit new pat
99334	Domicil/r-home visit est pat
99335	Domicil/r-home visit est pat
99336	Domicil/r-home visit est pat
99337	Domicil/r-home visit est pat
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient
99344	Home visit new patient
99345	Home visit new patient
99347	Home visit est patient
99348	Home visit est patient
99349	Home visit est patient
99350	Home visit est patient
99495	Trans care mgmt 14 day disch
99496	Trans care mgmt 7 day disch
99497	Advncd care plan 30 min

Approved Preventive Health Services

HCPCS Code	Short Descriptor
G0101	Ca screen; pelvic/breast exam
G0102*	Prostate ca screening; dre
G0117*	Glaucoma scrn hgh risk direc
G0118*	Glaucoma scrn hgh risk direc
G0296	Visit to determ LDCT elig
G0402	Initial preventive exam
G0436	Tobacco-use counsel 3-10 min
G0437	Tobacco-use counsel >10
G0438	Ppps, initial visit
G0439	Ppps, subseq visit
G0442	Annual alcohol screen 15 min
G0443	Brief alcohol misuse counsel
G0444	Depression screen annual
G0445	High inten beh couns std 30 min
G0446	Intens behave ther cardio dx
G0447	Behavior counsel obesity 15 min
Q0091	Obtaining screen pap smear

**Coinsurance and deductible are not waived*

Mental Health Services

HCPCS Code	Short Descriptor
90791	Psych diagnostic evaluation
90792	Psych diag eval w/med srvc
90832	Psytx pt&/family 30 minutes
90834	Psytx pt&/family 45 minutes
90837	Psytx pt&/family 60 minutes
90839	Psytx crisis initial 60 min
90845	Psychoanalysis

Effective January 1, 2016 CPT code 99490 (chronic care management) is paid based on the PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC claim.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



MLN Matters® Number: SE1611 **Revised**

Related Change Request (CR) #: N/A

Related CR Release Date: N/A

Effective Date: October 1, 2016

Related CR Transmittal #: N/A

Implementation Date: October 3, 2016

Rural Health Clinics (RHCs) Healthcare Common Procedure Coding System (HCPCS) Reporting Requirement and Billing Updates

Note: This article was revised on August 2, 2016 to show in Table 1 that codes G0436 and G0437 are replaced by 99406 and 99407, respectively, on October 1, 2016. All other information remains the same.

Provider Types Affected

This MLN Matters® Special Edition Article is intended for Rural Health Clinics (RHCs) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

This article provides information to assist RHCs in meeting the requirements to report the HCPCS code for each service furnished along with the revenue code on claims to Medicare effective for dates of service on or after April 1, 2016. Make sure your billing staff is aware of these instructions.

Background

From April 1, 2016, through September 30, 2016, all charges for a visit will continue to be reported on the service line with the qualifying visit HCPCS code, minus any charges for preventive services, using revenue code 052x for medical services and/or revenue code 0900 for mental health services. This guidance is available in MLN Matters Article MM9269 at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9269.pdf>. The RHC Qualifying Visit List

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(QVL) can be accessed on the RHC Center Page located at <https://www.cms.gov/center/provider-type/rural-health-clinics-center.html>.

In April 2016, CMS instructed RHCs to hold claims only for a billable visit shown in red on the RHC QVL until October 1, 2016. Upon billing these claims and/or for claim adjustments beginning on October 1, 2016, RHCs shall add modifier CG (policy criteria applied) to the line with all the charges subject to coinsurance and deductible. The subsequent paragraph explains modifier CG further.

Beginning on October 1, 2016, the MACs will accept modifier CG on RHC claims and claim adjustments. RHCs shall report modifier CG on one revenue code 052x and/or 0900 service line per day, which includes all charges subject to coinsurance and deductible for the visit. For RHCs, the coinsurance is 20 percent of the charges. Therefore, coinsurance and deductible will be based on the charges reported on the revenue code 052x and/or 0900 service line with modifier CG. RHCs will continue to be paid an all-inclusive rate (AIR) per visit.

Coinsurance and deductible are waived for the approved preventive health services in Table 1. When a preventive health service is the primary service for the visit, RHCs should report modifier CG on the revenue code 052x service line with the preventive health service. Medicare will pay 100% of the AIR for the preventive health service.

Table 1: Approved Preventive Health Services with Coinsurance and Deductible Waived

HCPSC/CPT Code	Short Descriptor
G0101	Ca screen; pelvic/breast exam
G0296	Visit to determ LDCT elig
G0402	Initial preventive exam
99406	Tobacco-use counsel 3-10 min
99407	Tobacco-use counsel >10
G0438	Ppps, initial visit
G0439	Ppps, subseq visit
G0442	Annual alcohol screen 15 min
G0443	Brief alcohol misuse counsel
G0444	Depression screen annual
G0445	High inten beh couns std 30 min
G0446	Intens behave ther cardio dx
G0447	Behavior counsel obesity 15 min
Q0091	Obtaining screen pap smear

Note: HCPCS code G0436 and G0437 will be discontinued effective 10/1/2016. CPT codes 99406 and 99407 are the remaining codes for tobacco cessation counseling. The beneficiary copayment is waived for CPT codes 99406 and 99407.

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Each additional service furnished during the visit should be reported with the most appropriate revenue code and charges greater to or equal to \$0.01. The additional service lines are for informational purposes only. MACs will continue to package/bundle the additional service lines, which do not receive the AIR.

When the patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day, the subsequent medical service should be billed using revenue code 052x and modifier 59. Beginning on October 1, 2016, RHCs can also report modifier 25 to indicate the subsequent visit was distinct or independent from an earlier visit furnished on the same day. When modifier 59 or modifier 25 is reported, RHCs will receive the AIR for an additional visit. This is the only circumstance in which modifier 59 or modifier 25 should be used.

Finally, note that the HCPCS reporting requirements have no impact in the way that telehealth or chronic care management services are reimbursed.

Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html>.

Document History

- May 9, 2016 – Initial Issuance.
- August 2, 2016 - This article was revised to show in Table 1 that codes G0436 and G0437 are replaced by 99406 and 99407, respectively, on October 1, 2016.

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Care Management Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Frequently Asked Questions

December 2019

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I. Care Management Services – General

Q1. What are care management services?

A1. Care management services in RHCs and FQHCs include the following 4 services:

- Transitional care management (TCM)
- Chronic care management (CCM)
- General behavioral health integration (BHI)
- Psychiatric Collaborative Care Model (CoCM)

Q2. Are care management services considered RHC and FQHC services?

A2. Yes, care management services are RHC and FQHC services.

Q3. Are RHCs and FQHCs required to provide TCM, CCM, general BHI, or psychiatric CoCM services?

A3. No. These structured care management services are in addition to any routine care coordination services already furnished as part of an RHC or FQHC visit.

Q4. Where can I find information on the requirements for each of the care management services?

A4. Please see Addendum I of this FAQ document for information on RHC and FQHC requirements and payment for CCM, General BHI, and Psychiatric CoCM. Information is also available on the RHCs and FQHCs webpages:

<https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html>

<https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html>

II. Care Management Services – Billing, Claims Processing, and Payment

Q5. How do RHCs and FQHCs bill for care management services and how are they paid?

A5. Care Management services are billed and paid as follows:

TCM: For TCM services furnished on or after January 1, 2013, TCM services can be billed by adding CPT code 99495 or CPT code 99496 to an RHC or FQHC claim, either alone or with other payable services. If it is the only medical service provided on that day with an RHC or FQHC practitioner it is paid as a stand-alone billable visit. If it is furnished on the same day as another visit, only one visit is paid.

CCM: For CCM services furnished between January 1, 2016 and December 31, 2017, CCM services can be billed by adding CPT code 99490 to an RHC or FQHC claim, either alone or with other payable services. Payment is based on the Physician Fee Schedule (PFS) national average non-facility payment rate for CPT code 99490.

For CCM services furnished on or after January 1, 2018, CCM services can be billed by adding the general care management G code, G0511, to an RHC or FQHC claim, either alone or with other payable services. Payment is set annually at the average of the national non-facility PFS payment rate for CPT codes 99490 (20 minutes or more of CCM services), 99487 (60 minutes or more of complex CCM services), and 99484 (20 minutes or more of general behavioral health integration services).

For CCM services furnished on or after January 1, 2019, CCM services can be billed by adding the general care management G code, G0511, to an RHC or FQHC claim, either alone or with other payable services. Payment is set annually at the average of the national non-facility PFS payment rate for CPT codes 99490 (20 minutes or more of CCM services), 99487 (60 minutes or more of complex CCM services), CPT code 99491 (30 minutes or more of CCM services furnished by an RHC or FQHC practitioner) and 99484 (20 minutes or more of general behavioral health integration services).

General BHI: For general BHI services furnished on or after January 1, 2018, general BHI services can be billed by adding the general care management G code, G0511, to an RHC or FQHC claim, either alone or with other payable services. Payment is set annually at the average of the national non-facility PFS payment rate for CPT codes 99490 (20 minutes or more of CCM services), 99487 (60 minutes or more of complex CCM services), and 99484 (20 minutes or more of general behavioral health integration services).

Psychiatric CoCM: For psychiatric CoCM services furnished on or after January 1, 2018, psychiatric CoCM services can be billed by adding the psychiatric CoCM G code, G0512, to an RHC or FQHC claim, either alone or with other payable services. Payment is set annually at the average of the national non-facility PFS payment rate for CPT codes 99492 (70 minutes or more of initial psychiatric CoCM services) and CPT code 99493 (60 minutes or more of subsequent psychiatric CoCM services).

Q6. What are the 2019 payment rates for care management services in RHCs and FQHCs?

A6. The 2019 care management payment rates are:

TCM (CPT code 99495 or 99496) – Same as payment for an RHC or FQHC visit

CCM or General BHI (HCPCS code G0511) – The 2019 rate is \$67.03.

Psychiatric CoCM (HCPCS code G0512) - The 2019 rate is \$145.96.

Q6a. What are the 2020 payment rates for care management services in RHCs and FQHCs?

A6a. The 2020 care management payment rates are:

TCM (CPT code 99495 or 99496) – Same as payment for an RHC or FQHC visit

CCM or General BHI (HCPCS code G0511) – The 2020 rate is \$66.77.

Psychiatric CoCM (HCPCS code G0512) - The 2020 rate is \$141.83.

Q7. Will the payment rate change?

A7. All payment rates are adjusted annually. The RHC TCM rate is the same as the RHC All-Inclusive Rate (AIR), which is adjusted annually based on the Medicare Economic Index. The FQHC TCM rate is the lesser of the FQHC's charges or the FQHC PPS rate, which is adjusted annually based on the FQHC Market Basket. The payment rates for general care management and psychiatric CoCM services are updated annually based on updates to the CCM, general BHI, and psychiatric CoCM codes in the PFS.

Q8. Will the payment methodology for care management services change?

A8. We will be reviewing available data over the next several years as more RHCs and FQHCs furnish these services. If the data indicates that a weighted average may be more appropriate in determining the payment rates, we would consider proposing a revision to the methodology. Any changes to the payment methodology would be undertaken through future notice and rulemaking.

Q9. Could new care management services be added in the future?

A9. If new care management services become available, we will evaluate them to determine their applicability to RHCs and FQHCs. The addition of any new codes or services would be undertaken through future notice and rulemaking.

Q10. Will claims submitted with CPT 99490 be paid?

A10. Claims with CPT code 99490 for CCM services furnished on or before December 31, 2017, will be processed and paid. Service lines reported with CPT code 99490 will be denied for dates of service on or after January 1, 2018.

Q11. Will claims with CPT codes 99487, 99484, or 99493 be paid?

A11. No. RHCs and FQHCs are required to bill for care management services using G0511 or G0512.

Q12. Do coinsurance and deductibles apply to care management services?

A12. Coinsurance and deductibles apply to all care management services in RHCs, and coinsurance applies to all care management services in FQHCs.

Q13. If a patient cannot afford the copayment but would benefit from this service, can the copayment be waived?

A13. The coinsurance for care management services cannot be waived, however, many RHCs and FQHCs offer financial assistance for patients who qualify.

Q14. How is coinsurance determined for care management services?

A14. Coinsurance is the lesser of the submitted charges or the payment rate.

Q15. What are the care management CPT codes and rates for practitioners billing under the PFS?

A15. The CPT codes for practitioners billing under the PFS are:

TCM - CPT code 99490 (Moderate Complexity), CPT code 99496 (High Complexity)

CCM - CPT code 99490 (≥ 20 minutes), CPT code 99487 (≥ 60 minutes complex), CPT 99491 (≥ 30 minutes, practitioner furnished)

General BHI - CPT code 99484 (≥ 20 minutes)

Psychiatric CoCM - CPT code 99492 (Init. ≥ 70 min.), CPT code 99493 (Subseq. ≥ 60 min.)

The care management rates paid under the PFS can be found at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSLookup/index.html?redirect=/pfslookup/02_pfssearch.asp

Q16. Are care management services required to be billed on a claim with an RHC or FQHC visit?

A16. No. Care management services can be billed either alone or on a claim with an RHC or FQHC billable visit.

Q17. Will care management services be paid in addition to an RHC or FQHC visit?

A17. Yes. If care management services are billed on the same claim as an RHC or FQHC visit, both will be paid.

Q18. If an RHC submits a claim for a billable visit and a care management service, is the total payment subject to the RHC payment limit?

A18. Except for TCM, which is paid as an RHC visit, payments for G0511 and G0512 are not factored in to the RHC AIR. The RHC would be paid 80% of their rate for the billable visit, subject to the RHC payment limit, plus 80% of the charges for care management.

Q19. If an FQHC submits a claim for a billable visit and a care management service, would these be added together to determine the payment?

A19. No. The FQHC would be paid 80% of the lesser of its charges or the fully adjusted PPS rate for the billable visit, plus 80% of the charges for care management.

Q20. What revenue code should be used for care management services?

A20. Care management services should be reported with revenue code 052x.

Q21. What date of service should be used on the claim?

A21. The service period for care management services is a calendar month. The date of service can be the date that the requirements to bill for the service have been met for that month, or any date after that but on or before the last day of the month.

Q22. When should the claim be submitted?

A22. The claim can be submitted when the requirements to bill for the services have been met, or any time after that within the timely filing requirement period, which is one year from the date of service (Pub 100-04, chapter 1, section 70).

Q23. What diagnosis code should be used when billing for care management services? Are there specific conditions that qualify?

A23. All claims must include a diagnosis code and practitioners should use the most appropriate diagnosis code for the patient.

Q24. Can care management costs such as software or management oversight be included on the cost report?

A24. Yes. Any cost incurred as a result of the provision of RHC and FQHC services, including care management, is a reportable cost and must be included in the Medicare cost report. Direct costs for care management services are reported in the "*Other than RHC/FQHC Services*" section of the cost report and are not used in determining the RHC AIR or the FQHC PPS rate.

Q25. Can RHCs and FQHCs bill for more than one care management service in the same month for an individual? For example, could an RHC or FQHC furnish 20 minutes of CCM services at the beginning of the month, and 70 minutes of psychiatric services later in the month, and bill for both?

A25. No. RHCs and FQHCs can only bill one care management service for an individual per month.

Q26. Can an RHC or FQHC bill HCPCS codes G0511 or G0512 twice in the same month if more than twice the required amount of time is used?

A26. No. The specified amounts of time are minimum requirements and there is no additional payment if more time is spent.

Q27. Can RHCs and FQHCs bill for care management during the same month as another facility that bills for care management?

A27. RHCs and FQHCs can bill for care management services if all the requirements for billing are met and there is no overlap of dates of services with another entity billing for care management services.

Q28. Can RHCs and FQHCs bill for care management services furnished to a patient in a skilled nursing facility (SNF)?

A28. RHCs and FQHCs cannot bill for care management services provided to SNF inpatients in Medicare Part A covered stays because the facility is being paid under Part A for extensive care planning and care coordination services. However, if the patient is not in the Part A SNF for the entire month, the RHC or FQHC could bill for care management services furnished to the patient while the patient is not in the Part A SNF if the care management requirements are met.

Q29. Can RHCs and FQHCs bill for care management services provided to beneficiaries in nursing facilities or assisted living facilities?

A29. If the nursing facility or assisted living facility is not furnishing care management services and the RHC or FQHC has met the billing requirements, then the RHC or FQHC can bill for care management services furnished to beneficiaries in nursing or assisted living facilities.

Q30. Are there other restrictions on when care management services can be billed?

A30. RHCs and FQHCs cannot bill for care management services during the same service period that care management is being provided by another facility or practitioner. This includes home health care supervision, hospice care supervision, certain ESRD services, or any other services that would result in duplicative payment for care management services.

Q31. Can RHCs and FQHCs bill HCPCS code G0511 if 10 minutes of general care management (CCM or general BHI services) are furnished at the end of one month and another 10 minutes are furnished at the beginning of the next month?

A32. No. A minimum of 20 minutes of CCM or general BHI services are required to be furnished within the calendar month, not during a 30 day period.

Q33. Can RHCs and FQHCs bill HCPCS code G0512 if 30 minutes of psychiatric CoCM services are furnished at the end of one month and another 30 minutes are furnished at the beginning of the next month?

A33. No. A minimum of 60 minutes of psychiatric CoCM services are required to be furnished within the calendar month, not during a 30 day period.

Q34. If 2 or more RHC or FQHC practitioners or auxiliary staff discuss a patient's care, would time for each of them be counted towards the minimum requirements?

A34. No. If 2 or more RHC or FQHC practitioners or auxiliary staff people are discussing the patient's care coordination, only one person's time would be counted. For example, if 2 people are discussing care for 5 minutes, then 5 minutes would be counted, not 10 minutes.

Q35. Can care management services be conducted by auxiliary personnel in a location other than the RHC or FQHC?

A35. The direct supervision requirements for auxiliary personnel have been waived for TCM, CCM, general BHI, and psychiatric CoCM services furnished by RHCs and FQHCs. These services can be furnished by auxiliary personnel under general supervision of the RHC or FQHC practitioner. General supervision does not require the RHC or FQHC practitioner to be in the same building or immediately available, but it does require the services to be furnished under the RHC or FQHC practitioner's overall supervision and control.

Q36. Is contact with the patient every month necessary to bill for care management services if the billing requirements are met?

A36. No, although we expect that RHCs and FQHCs will want to keep the patient informed about their care management, especially since this is a service that the patient is paying for but is not typically visible to them.

Q37. Can the time spent performing secure messaging or other asynchronous non face-to face consultation methods such as email count toward the minutes required to bill for care management services?

A37. Activities that are within the scope of service elements may be counted toward the time required for billing if they are measurable and can be documented.

Q38. Can smartphone medication adherence reporting from individual patient or caregiver back to their care manager count towards the minutes required to bill for care management services?

A38. No. Patient or caregiver time is not counted towards the time required to bill for care management services.

Q39. Are psychiatric consultant services for psychiatric CoCM separately billable?

A39. No. All services furnished as part of psychiatric CoCM are included in the psychiatric CoCM payment (HCPCS code G0512) and cannot be separately billed to Medicare wither by the RHC or FQHC or by the psychiatric consultant.

Q40. Can RHCs and FQHCs bill care management services for Medicare Advantage patients?

A40. RHCs and FQHCs should consult the MA plan for billing information.

III. Care Management Services – Program Requirements

a. Initiating Visit

Q41. Is an initiating visit required for all patients before care management services can begin?

A41. Yes. An initiating visit with an RHC or FQHC practitioner (primary care physician, NP, PA, or CNM) is required before CCM, general BHI, or psychiatric CoCM services can be furnished. The initiating visit must be an evaluation and management (E/M) visit, annual wellness visit (AWV), or an initial preventive physical exam (IPPE), and must occur no more than one-year prior to commencing care coordination services.

Q42. Does care management need to be discussed during the initiating visit before care management services can begin?

A42. Care management services do not need to have been discussed during the E/M, AWV, or IPPE visit in order to begin care management services. However, prior to the commencement of care management services, consent must be obtained. Consent may be verbal (written consent is not required) but must be documented in the medical record.

Q43. Who can determine if a patient is eligible for care management services?

A43. The RHC or FQHC practitioner (primary care physician, NP, PA, or CNM) determines if the patient meets the criteria for care management services and if they are likely to benefit from care management services.

Q44. Can a clinical social worker, clinical psychologist, or psychiatrist determine that a patient meets the criteria for general BHI or psychiatric CoCM services and furnish the initiating visit?

A44. General BHI and psychiatric CoCM are both defined models of care that focus on integrative treatment of patients with primary care and mental or behavioral health conditions. A social worker, clinical psychologist, or psychiatrist can recommend to the primary care practitioner that a patient would benefit from general BHI or psychiatric CoCM services, but only a member of the primary care team can make the eligibility determination and furnish the initiating visit.

Q45. Does the patient need to have a mental health encounter before general BHI or psychiatric CoCM services can be furnished?

A45. No. Only an initiating visit (E/M, AWV, or IPPE) with the primary care team (primary care physician, NP, PA, or CNM) within 1 year prior to commencement of care management services is required. The primary care practitioner determines if the patient is eligible for general BHI or psychiatric CoCM. An initial assessment by the behavioral health manager is part of the care management payment and is not separately billable.

Q46. Can the initiating visit be furnished via telehealth?

A46. No. RHCs and FQHCs are not authorized to serve as distant sites for telehealth services.

Q47. Does the time spent during the E/M, AWV, or IPPE discussing care management services count towards the time required to bill for these services?

A47. No. The E/M, AWV, or IPPE is separately paid and the time cannot be counted towards the required time for billing HCPCS codes G0511 or G0512.

b. Consent and Opting Out

Q48. When is patient consent for care management services required?

A48. Patient consent is required before time is counted toward care management services.

Q49. How often is consent required for care management services?

A49. If a patient continues to receive care management services from the same RHC or FQHC, consent is only required when the care management service is initiated.

Q50. Does the patient have to sign a consent form for care management services?

A50. Consent can be verbal (written consent is not required), but must be documented in the medical record.

Q51. If a patient has consented to receive CCM services and later is switched to general BHI or psychiatric CoCM services, does the patient have to provide additional consent?

A51. Yes. A patient that has consented to receive CCM services would need to separately consent to receiving general BHI or psychiatric CoCM services to ensure that they are aware of the change in services and any differences in copayment amounts.

Q52. How does a patient opt out of care management services?

A52. A patient can opt out of care management services by notifying the RHC or FQHC that he/she does not want to continue this service. The date of revocation must be recorded in the patient's medical record.

Q53. If a patient opts out of care management services and later wants to resume receiving care management services, is consent required?

A53. Yes.

Q54. Once a patient has consented to receive care management services, do the services have to be provided every month?

A54. Care management services should only be furnished on an as-needed basis. The consent for receiving care management services remains in effect until revoked, even if no CCM services are furnished.

c. Care Plan

Q55. How often does the care plan need to be reviewed and updated?

A55. There are no specific requirements for updating the care plan. It should be reviewed and updated as appropriate for the patient's care.

Q56. Should the general BHI and psychiatric CoCM care plans also include physical health issues?

A56. Although physical health care planning is not a required element of the general BHI or psychiatric CoCM care plan, physical health and extended care team members should be included as appropriate to assure that all aspects of care are coordinated.

Q57. Is certified EHR technology required for billing HCPCS code G0511 when BHI services are furnished?

A57. Certified EHR technology is a requirement for CCM, but it is not a requirement for general BHI or psychiatric CoCM services. To bill the new HCPCS code G0511, an RHC or FQHC must meet the requirements for either CCM (CPT code 99490 or CPT code 99487) or general BHI (CPT code 99484). If the requirements for CPT code 99484 are met, the code can be billed and certified EHR technology is not required.

IV. Care Management Services - Care Team

a. Behavioral Health Care Manager

Q58. What credentials are required for the CoCM behavioral health care manager?

A58. The behavioral health care manager must have formal education or specialized training in behavioral health such as social work, nursing, or psychology, and must have a minimum of a bachelor's degree in a behavioral health field (such as in clinical social work or psychology), or be a clinician with behavioral health training, including RNs and LPNs.

Q59. Can a certified addiction counselor serve as the behavioral health care manager?

A59. A certified addiction counselor can serve as the behavioral health care manager if they meet the behavioral health care manager requirements listed in the previous response.

Q60. Can the RHC or FQHC contract with another company for the services of the behavioral health care manager?

A60. The behavioral health care manager furnishes both face-to-face and non-face-to-face services. This person works under the general supervision of the RHC or FQHC practitioner and may be employed by or working under contract to the RHC or FQHC, not to another company.

Q61. Can someone other than the health care manager administer screenings and enter data for the registry?

A61. RHCs and FQHCs can delegate duties as appropriate. It is the responsibility of the RHC or FQHC to assure that personnel meet any requirements and to manage any delegation of duties and supervision as appropriate.

b. Psychiatric Consultant

Q62. What credentials are required for the psychiatric CoCM psychiatric consultant?

A62. The psychiatric consultant must be a medical professional trained in psychiatry and qualified to prescribe the full range of medications.

Q63. Does the psychiatric consultant have any face-to-face contact with the patient receiving psychiatric CoCM services?

A63. No. The psychiatric consultant is a consultant to the RHC or FQHC. They are not required to be on site or have direct contact with the patient, and they do not prescribe medications or furnish treatment to the beneficiary directly.

Q64. Can a psychiatric mental health nurse practitioner (PMH-NP) serve as the psychiatric consultant to RHCs and FQHCs that are furnishing psychiatric CoCM?

A64. Any medical professional, including a PMH-NP, who is trained in psychiatry and qualified to prescribe the full range of medications serves would meet the requirements to serve as a psychiatric CoCM psychiatric consultant.

c. Auxiliary Staff

Q65. Can a pharmacist furnish CCM services?

A65. Yes. Pharmacists are considered auxiliary staff and can provide CCM services under general supervision once the service is initiated by an RHC or FQHC practitioner.

Addendum I
CCM, General BHI, and Psychiatric CoCM Requirements and Payment
For RHCs and FQHCs

Requirements	CCM	General BHI	Psychiatric CoCM
Initiating Visit	An E/M, AWW, or IPPE visit occurring no more than one-year prior to commencing care coordination services.	Same	Same
	Furnished by a primary care physician, NP, PA, or CNM.	Same	Same
	Separately billable RHC/FQHC visit.	Same	Same
Beneficiary Consent	Obtained during or after initiating visit and before provision of care coordination services by RHC or FQHC practitioner or clinical staff.	Same	Same
	Written or verbal, documented in the medical record.	Same	Same
	Includes information: <ul style="list-style-type: none"> On the availability of care coordination services and applicable cost-sharing; That only one practitioner can furnish and be paid for care coordination services during a calendar month; That the patient has right to stop care coordination services at any time (effective at the end of the calendar month); and That the patient has given permission to consult with relevant specialists. 	Same	Same
Billing Requirements	At least 20 minutes of care coordination services per calendar month that is: <ul style="list-style-type: none"> Furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM; and Furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision. 	Same	At least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months of psychiatric CoCM services that is: <ul style="list-style-type: none"> Furnished under the direction of the RHC or FQHC primary care practitioner; and Furnished by an RHC or FQHC practitioner or behavioral health care manager under general supervision.
Patient Eligibility	Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, and place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline	Any behavioral health or psychiatric condition being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC	Same As General BHI

Requirements	CCM	General BHI	Psychiatric CoCM
		practitioner, warrants BHI services	
Requirement Service Elements	<p>Includes:</p> <ul style="list-style-type: none"> • Structured recording of patient health information using Certified EHR Technology and includes demographics, problems, medications, and medication allergies that inform the care plan, care coordination, and ongoing clinical care; • 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week, and continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments; • Comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications; • Comprehensive care plan including the creation, revision, and/or monitoring of an electronic care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed; • Care plan information made available electronically (including fax) in a timely manner within and outside the RHC or FQHC as appropriate and a copy of the plan 	<p>Includes:</p> <ul style="list-style-type: none"> • Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; • Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; • Facilitating and coordinating treatment (such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation); and • Continuity of care with a designated member of the care team. 	<p>Includes:</p> <p><u>RHC or FQHC primary care practitioner:</u></p> <ul style="list-style-type: none"> • Direct the behavioral health care manager or clinical staff; • Oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed; and • Remain involved through ongoing oversight, management, collaboration and reassessment <p><u>Behavioral Health Care Manager:</u></p> <ul style="list-style-type: none"> • Provide assessment and care management services, including the administration of validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; provision of brief psychosocial interventions; ongoing collaboration with the RHC or FQHC practitioner; maintenance of the registry; acting in consultation with the psychiatric consultant; • Be available to provide services face-to-face with the beneficiary; having a continuous relationship with the patient and a collaborative, integrated

Requirements	CCM	General BHI	Psychiatric CoCM
	<p>of care given to the patient and/or caregiver;</p> <ul style="list-style-type: none"> • Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities; timely creation and exchange/transmit continuity of care document(s) with other practitioners and providers; • Coordination with home- and community-based clinical service providers, and documentation of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits in the patient's medical record; and • Enhanced opportunities for the patient and any caregiver to communicate with the practitioner regarding the patient's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods. 		<p>relationship with the rest of the care team; and</p> <p><u>Psychiatric Consultant:</u></p> <ul style="list-style-type: none"> • Participate in regular reviews of the clinical status of patients receiving CoCM services; • Advise the RHC or FQHC practitioner regarding diagnosis, options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; making adjustments to behavioral health treatment for beneficiaries who are not progressing; managing any negative interactions between beneficiaries' behavioral health and medical treatments; and • Facilitate referral for direct provision of psychiatric care when clinically indicated
Billing Code	G0511	G0511	G0512
Payment	TBD (Average of CPT codes 99490, 99487 and 99484)	TBD (Average of CPT codes 99490, 99487 and 99484)	TBD (Average of CPT 99492 and 99493)

Virtual Communication Services in Rural Health Clinics (RHCs) and

Federally Qualified Health Centers (FQHCs)

Frequently Asked Questions

December 2018

1. What are “virtual communication services” for RHCs and FQHCs?

Answer: In the 2019 Physician Fee Schedule (PFS) Final Rule, CMS finalized a policy that, effective January 1, 2019, RHCs and FQHCs can receive payment for virtual communication services when at least 5 minutes of communication technology-based or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient who has had an RHC or FQHC billable visit within the previous year, and both of the following requirements are met:

- The medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and
- The medical discussion or remote evaluation does not lead to an RHC or FQHC visit within the next 24 hours or at the soonest available appointment.

2. What is the payment rate for the new code G0071 (Virtual Communication Services)?

Answer: HCPCS code G0071 is set at the average of the national non-facility PFS payment rates for HCPCS code G2012 (communication technology-based services) and

HCPCS code G2010 (remote evaluation services) and is updated annually based on the PFS national nonfacility payment rate for these codes. For 2019, the payment amount for code G0071 will be \$13.69 (average of HCPCS codes G2012 and G2010).

3. Will claims submitted with HCPCS codes G2012 or G2010 be paid?

Answer: No. RHCs and FQHCs are required to bill for virtual communication services using G0071.

4. Are telehealth and virtual communication services the same thing?

Answer: No. Although both telehealth and virtual communication services use technology to communicate, these are separate and distinct services. Telehealth services are considered a substitute for an in-person visit, and are therefore paid at the same rate as it would have been had it been furnished in person. With some exceptions, telehealth services require the use of interactive audio and digital telecommunication systems that permit real-time communication between the practitioner at the distant site and the beneficiary at the originating site. The communication technology-based and remote evaluation services that we finalized are not a substitute for a visit, but are instead brief discussions with the RHC or FQHC practitioner to determine if a visit is necessary. If the discussion between the RHC or FQHC practitioner and the Medicare beneficiary results in a billable visit, then the usual RHC or FQHC billing would occur. The virtual communication G-code would only be separately payable if the discussion between the

RHC or FQHC practitioner does not result from or lead to an RHC or FQHC billable visit. The payment rate for communication technology-based services are valued based on the shorter duration of time and the efficiencies associated with the use of communication technology.

5. Are there any limitations on the number of times HCPCS code G0071 (Virtual Communication Services) can be billed for a single beneficiary?

Answer: No, there are no frequency limitations at this time.

6. What types of practitioners can furnish virtual communication services?

Answer: Communication technology-based and remote evaluation services are billable by RHCs and FQHCs only when the discussion requires the skill level of an RHC or FQHC practitioner. RHC and FQHC practitioners are physicians, nurse practitioners, physician assistants, certified nurse midwives, clinical psychologists, and clinical social workers. If the discussion could be conducted by a nurse, health educator, or other clinical personnel, it would not be billable as a virtual communication service.

7. Does coinsurance apply to HCPCS code G0071?

Answer: Coinsurance and deductibles apply to RHC claims for G0071 and coinsurance applies to FQHC claims for G0071. Coinsurance is 20 percent of the lesser of the charged

amount or the payment amount for code G0071. We are aware that coinsurance can be a barrier for some beneficiaries, but we do not have the statutory authority to waive the coinsurance requirement. RHCs and FQHCs should inform their patients that coinsurance applies, and provide information on the availability of assistance to qualified patients in meeting their cost sharing obligations, or any other programs to provide financial assistance, if applicable.

8. Is beneficiary consent required before virtual communication services can be furnished?

Answer: Beneficiary consent should be obtained before virtual communication services are furnished in order to bill for the service.

9. Do virtual communication services have to occur with the same RHC or FQHC practitioner that has previously treated the patient?

Answer: No. As long as the patient has had an RHC or FQHC billable visit within the previous year, virtual communication services can be furnished by any RHC or FQHC practitioner.

10. Will payment of this new code affect the RHC or FQHC payment rates?

Answer: No, the RHC AIR and the FQHC PPS would not be impacted by these changes. Services that are currently being furnished and paid under the RHC AIR or FQHC PPS payment methodology will not be affected by the ability of the RHC or FQHC to receive payment for additional services that are not included in the RHC AIR or FQHC PPS.

11. What types of communication technology can be used in order to bill for code G0071?

Answer: Virtual communication services would be initiated by the patient contacting the RHC or FQHC by a telephone call, integrated audio/video system, or through a store-and-forward method such as sending a picture or video to the RHC or FQHC practitioner for evaluation and follow up within 24 hours. The RHC or FQHC practitioner may respond to the patient's concern by telephone, audio/video, secure text messaging, email, or use of a patient portal.

12. If the RHC or FQHC practitioner contacts the patient to monitor their condition, could G0071 be billed?

Answer: No. Virtual communication services are initiated by the patient in order to determine if an RHC or FQHC visit or other care is necessary. If an RHC or FQHC practitioner contacts the patient to follow up on a previous visit, the cost of this contact would be included in the RHC AIR or FQHC PPS payment.

13. Can RHCs and FQHCs bill virtual communication services for Medicare Advantage patients?

Answer: RHCs and FQHCs should consult the MA plan for billing information.

14. Will secondary payors recognize HCPCS code G0071?

Answer: HCPCS codes are recognized by all secondary payors. In some cases, there may be a delay if the secondary payor has not yet updated their systems to accept new codes.

15. Are virtual communication services considered RHC and FQHC services?

Answer: Yes, virtual communication services are RHC and FQHC services.

16. Are RHCs and FQHCs required to provide virtual communication services? Is there a penalty if these services are not provided?

Answer: No, RHCs and FQHCs are not required to furnish virtual communication services and there is no penalty if they are not provided.

17. Do RHCs and FQHCs have to enroll and be approved in order to furnish and bill for virtual communication services?

Answer: No, there is no enrollment or approval process for virtual communication services. Any RHC or FQHC can bill for virtual communication services if all requirements are met.

18. Can RHCs and FQHCs bill G0071 during the same month that the patient is receiving care management services?

Answer: Yes, if all requirements for billing G0071 are met.

19. Can RHCs and FQHCs bill G0071 on the same claim as a billable visit?

Answer: G0071 can be billed either alone or on the same claim as a billable visit.

However, virtual communication services are not billable if an RHC or FQHC visit was furnished within the previous 7 days or the next 24 hours or soonest available appointment.

20. Can virtual communication services costs such as software or management oversight be included on the cost report?

Answer: Yes. Any cost incurred as a result of the provision of RHC and FQHC services, including virtual communication services, is a reportable cost and must be included in the Medicare cost report. Direct costs for virtual communication services are reported in the

“Other than RHC/FQHC Services” section of the cost report and are not used in determining the RHC AIR or the FQHC PPS rate.

21. Where can I find more information on virtual communication services?

Answer: Information is available in section 240 in Chapter 13 of the CMS Benefit Policy Manual, which is located on the RHCs and FQHCs webpages at

<https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html>, and

<https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html>.

The 2019 PFS proposed and final rule is located at:

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html)

[Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html).

State Operations Manual

Appendix G - Guidance for Surveyors: Rural Health Clinics (RHCs)

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Rural Health Clinic Survey Protocol

Introduction

The Rural Health Clinic (RHC) statutory provisions are set forth in Section 1861(aa) of the Social Security Act (the “Act”). Specifically, Section 1861(aa)(2)(K) of the Act requires Medicare participating RHCs to meet other requirements as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services at the RHC. In accordance with 42 CFR §405.2402, RHCs are required to be certified as in compliance with the Medicare Conditions for Certification (CfC) at 42 CFR Part 491, Subpart A in order to enroll in the Medicare program. Further, as required at 42 CFR §405.2403(a), as part of the agreement between the Medicare program and an RHC, the RHC agrees to maintain its compliance with the RHC CfCs. The goal of an RHC survey is to determine if the RHC is in compliance with the CfCs.

Determination of a facility’s compliance with the RHC CfCs is accomplished through:

- an off-site review of the facility’s location by the CMS Regional Office (RO), to determine whether the facility meets the location criteria at §491.5; and
- an on-site survey using observations, interviews, and document/record reviews to assess compliance with the rest of the CfCs.

In the case of initial applicants for RHC certification, to facilitate an efficient survey and certification process, CMS requires the applicant to complete and submit to the State Survey Agency (SA) Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program, as part of its application for certification. Facilities provide basic information related to their location and staffing on this document. To make efficient use of survey resources, SAs make a /preliminary assessment of the information contained on the Form CMS-29 prior to conducting a survey, to avoid conducting a survey of an ineligible location. However, since only the CMS RO may make a determination whether the RHC applicant has satisfied all Federal requirements, including the location and staffing requirements, the SA must not notify the applicant of the results of the SA’s preliminary assessment of the Form CMS-29. (See State Operations Manual (SOM) Section 2242A)

The on-site survey process focuses on an RHC’s delivery of patient care, including its organizational functions and processes for the provision of care. The RHC on-site survey is the means used to assess compliance with Federal health, safety and quality standards that will assure that patients receive safe, quality care and services.

Regulatory and Policy References

- General RHC definitions, Medicare participation requirements, RHC Medicare agreement, and provisions for termination of the RHC Medicare agreement are located at 42 CFR Part 405, Subpart X.
- The CfCs for RHCs are located at 42 CFR Part 491, Subpart A.
- General survey and certification requirements and survey authority are located at 42 CFR Part 488, Subpart A.
- Should an individual or entity/RHC refuse to allow immediate access upon reasonable request to either a SA or CMS surveyor, the Department of Health and Human Services, Office of Inspector General (OIG) may exclude the RHC from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. If a surveyor intends to make a request for immediate access with the threat of possible exclusion for non-compliance, the SA must first contact the CMS RO, which must then contact the OIG Administrative and Civil Remedies Branch at 202-619-1306.
- The CMS SOM, Publication 100-07, provides CMS policy regarding survey and certification activities.

All RHC surveys are unannounced. Do not provide existing RHCs or RHC applicants with advance notice of the survey.

Tasks in the Survey Protocol

The tasks included in a survey protocol for an RHC are:

Task 1	Off-Site Survey Preparation
Task 2	Entrance Activities
Task 3	Information Gathering/Investigation
Task 4	Preliminary Decision-Making and Analysis of Findings
Task 5	Exit Conference
Task 6	Post-Survey Activities

Task 1 – Off-Site Preparation

General Objectives

The objectives of this task are to make a preliminary assessment of whether the RHC applicant meets the basic location and staffing requirements and, if it does, to determine the size and composition of the survey team and analyze information about the RHC applicant in order to identify areas of potential focus during the survey. See SOM Section 2242 for detailed information about making the preliminary assessment of

compliance with the location requirements, as well as S&C 13-30, May 10, 2013 and S&C 15-09, November 14, 2014 for information on the process the ROs are to use when making determinations concerning RHC location compliance.

In the case of a recertification of an RHC, the objective of this task is to determine the size and composition of the survey team and analyze information about the RHC in order to identify areas of potential focus during the survey.

Review of other information about the RHC allows the SA (or RO for Federal teams) to develop a preliminary survey plan. Refer to the below section, **Assembling Background Information**, for more details.

A full or standard survey will be conducted if the purpose of the survey is for initial certification, recertification, or as part of the annual CMS representative sample validation survey program for deemed status providers and suppliers.

Surveys in response to a complaint or multiple complaints, or as a revisit to determine if a previously cited problem has been corrected, focus on the CfC(s) related to the complaint or on the CfC(s) for which deficiencies were previously identified. This does not preclude the scope of a complaint or revisit survey being expanded, if surveyors observe deficient practices related to other CfCs while on site. In the case of a deemed status RHC, the SA may only conduct a complaint survey when authorized to do so by the RO. (See Chapter 5 of the SOM, Sections 5075, 5100.1 and 5200.1)

Types of Surveys

Standard (or Full) surveys: Initial certification, recertification and representative sample validation requires assessment of the RHC's compliance with all CfCs.

- Initial surveys are conducted when a facility first seeks to participate in the Medicare program as an RHC and does not choose to seek deemed status based on accreditation by a CMS-approved Medicare RHC accreditation program.
- Recertification surveys are required for non-deemed status RHCs to reconfirm, at periodic intervals, the RHC's ongoing compliance with the CfCs.
- Representative sample validation surveys are conducted to support CMS's oversight of national accrediting organizations (AOs) whose Medicare accreditation programs have been recognized by CMS as suitable for deeming facilities as meeting the applicable Medicare CfCs or CoPs. CMS selects the facilities for this type of validation survey, and the SA must complete its survey no later than 60 days after the AO's survey. Although the primary purpose of the survey is to validate the AO's oversight, if substantial noncompliance is found by the SA and the RO concurs, the RO initiates appropriate enforcement actions. SAs may only survey a deemed status RHC when authorized to do so by the CMS RO.

Complaint or On-site Revisit Surveys: Generally, these types of survey are more narrowly focused than a full standard survey.

- A complaint is an allegation of noncompliance with Medicare health and safety standards. The purpose of a complaint survey is to determine the validity of the allegation and assess the current compliance of the RHC with those CfCs that are relevant to the substance of the allegation that triggered the survey. Surveyors assess compliance with all of the requirements of the condition(s) being investigated related to the complaint, just as they would on a full survey. It is not sufficient simply to review the clinical record of the patient that triggered the complaint.
- The purpose of the on-site revisit survey is to determine the RHC's current compliance with the CfC(s) for which the RHC was cited for condition-level noncompliance on a prior related standard or complaint survey. The SA must receive an acceptable Plan of Correction (PoC) from the RHC before it conducts a revisit survey.

Generally, complaints received by the SA or CMS concern specific cases or incidents that occurred in the past. However, CMS evaluates RHCs only for their current compliance or noncompliance at the time of the survey. Nevertheless, if an investigation of a complaint about a past event indicates there was a violation of one or more of the CfC requirements, and there is no evidence that the RHC subsequently implemented effective corrective action prior to the complaint survey, then the findings concerning the violation are documented on the Form CMS-2567, Statement of Deficiencies and PoC as evidence of current noncompliance. On the other hand, if an investigation shows that a past violation occurred, but the RHC subsequently implemented effective corrective action and the survey reveals no current noncompliant practices, then the RHC is in current compliance and is not cited for a deficiency based on the past noncompliance.

Survey Team Size and Composition

The SA (or the CMS RO for Federal teams) decides the composition and size of the team. In general, a standard, i.e., full, RHC survey includes one health standards surveyor who is on-site for one day, but individual circumstances may call for a larger team, or a shorter or longer period of time on-site. The following factors are considered when determining survey team size and the scheduled length of the survey:

- Size of the RHC, based on its number of patient exam rooms, hours of operation, and/or available information about its average monthly volume of patients;
- Whether the RHC has an historical pattern of serious deficiencies or complaints;
- Whether new surveyors are to accompany the surveyor as part of their training.

For a complaint or on-site revisit survey, only one surveyor will usually be needed and should be chosen based on their knowledge of the CfC(s) that will be reviewed during the survey.

RHC surveyors must have the necessary training and experience to conduct a survey. Completion of the Principles of Documentation Training Course is required. In addition, completion of the Basic RHC Surveyor training course is required for all RHC health standards surveyors, unless such training has not been offered by CMS in the previous two years. The RHC surveyor, or at least one member of a survey team, should be a registered nurse with hospital or RHC survey experience who has the expertise needed to determine if the facility is in compliance with the CfCs. New surveyors may accompany existing surveyor(s) prior to completing the required training but not as a team member.

Single Surveyor or Team Coordinator

An RHC survey may be conducted by one surveyor. The SA (or the RO for Federal teams) designates a Team Coordinator when the survey team consists of more than one surveyor. The surveyor, or Team Coordinator when applicable, is responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol. Responsibilities of the surveyor, or Team Coordinator when applicable, include:

- Acting as spokesperson to the RHC;
- Conducting the entrance and exit conferences;
- Providing other on-going feedback, as appropriate, to RHC leadership on the status of the survey;
- When there is more than one surveyor, assigning team members specific survey tasks;
- Facilitating time management during the survey;
- Encouraging ongoing communication among team members, when applicable;
- Evaluating team progress in completing the survey and coordinating team meetings, when applicable;
- Preparing the Form CMS-2567, Statement of Deficiencies and PoC, as well as all other reports/documentation required by CMS. If there is a survey team, coordinating the preparation of the documentation.

Assembling Background Information

Surveyors must prepare for the on-site survey offsite, in order to make efficient use of the time onsite at the RHC. The type of background material to be gathered from the SA's files and/or the CMS database prior to the on-site survey includes:

- Basic characteristics of the RHC, including the facility's ownership, hours of operation, size, and types of services offered. The most recent Form CMS-29 Verification of Clinic Data - Rural Health Clinic Program shows the RHC's location, basic staffing information and type of control. Other sources of information may include the SA's licensure file;
- Any additional information publicly available about the RHC, e.g., from its Website, media reports, etc.;
- Any available information on the physical layout of the RHC;
- For existing RHCs, determine whether a mid-level Staffing Waiver has been issued and is still in effect;
- For existing RHCs, determine whether the clinic has applied to offer Visiting Nurse Services (VNS) and has been found by the CMS RO to be eligible to offer VNS;
- Survey history and results of previous Federal and State surveys. In the case of a complaint survey, information on whether there were similar complaints investigated in the past;
- Directions to the RHC

If the survey involves more than one surveyor, the Team Coordinator will arrange an offsite preparation meeting. During the meeting, or independently in the case of a single surveyor, the survey preparation should include consideration of:

- Any significant information identified from the background information assembled;
- Whether there are CfCs requiring particular attention;
 - In the case of a complaint survey, the SA – or, in the case of a deemed status RHC, the RO - identifies in advance of the onsite investigation which CfCs will be surveyed for compliance;
 - In the case of an on-site revisit survey, surveyors will focus on the RHC's current compliance with those CfCs where deficiencies were cited on the most recent related Form CMS-2567. Surveyors also review the RHC's PoC and will look for evidence while onsite that the plan was implemented. (However, surveyors may

not assume that implementation of the plan always means that the RHC is in substantial compliance with the CfC. It is possible that a PoC may be implemented, but is not sufficient to bring the RHC into compliance.);

- Preliminary team member assignments;
- Any questions the team has about how they will evaluate the CfCs;
- Date, location, and time team members will meet to enter the facility;
- When daily team meetings will take place, if needed; and
- The anticipated date and time of the Exit Conference.

Note: Conduct RHC surveys during the RHC's normal business hours. All surveys are unannounced. Do not provide RHC applicants or existing RHCs with advance notice of the survey.

Resources:

The following resources are useful to bring on surveys:

- Appendix G – Guidance for Surveyors: Rural Health Clinics;
- Appendix Q - Immediate Jeopardy;
- Copy of the regulations at 42 CFR §§ 405.2402 – 2404, concerning the RHC basic requirements, Medicare agreement and termination;
- Several copies of the regulatory language located at 42 CFR § 489.53 regarding the basis for terminating a provider/supplier agreement which applies to RHCs; and
- Several copies of the regulatory language at 42 CFR 1001.1301 regarding the consequences of failure to permit the survey team access to the facility;

Task 2 – Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the RHC staff and obtain the information needed to conduct the survey.

General Procedures

Arrival

For surveys requiring more than one surveyor, the entire survey team should enter the RHC together. Upon arrival, the surveyor(s) must present identification. If the RHC denies entrance to the facility or otherwise tries to limit required survey activities, explain that this may be grounds for terminating the RHC's participation in Medicare. (See 42 CFR §1001.1301.)

If the surveyor(s) encounter any problems onsite, they should feel free to contact the SA manager or the RO for guidance. For instance, if RHC staff will not let a surveyor into the facility even after they're informed of the possible sanctions that can be imposed for restricting access to their facility, a call to the SA or RO would be appropriate.

The surveyor, or Team Coordinator when more than one surveyor is assigned, announces to the RHC's Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not onsite or readily available, the surveyor or Team Coordinator asks that the Administrator be notified that a Federal survey is being conducted. Do not delay the survey because the Administrator is not available.

Entrance Conference

The entrance conference sets the tone for the entire survey. The surveyor(s) must be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief.

During the entrance conference, the surveyor or Team Coordinator:

- Explains the purpose and scope of the survey (initial certification or recertification; representative sample validation; complaint investigation; revisit);
- Briefly describes the survey process;
- Introduces themselves and/or the survey team members, including any additional surveyors who may join the team at a later time, and discusses in general what the surveyors will do and the various documents they may request;
- Clarifies that all areas of the RHC may be surveyed, but emphasizes that the survey will not interfere with the provision of patient care and will take all standard precautions to avoid any infection control breaches; patients will be asked by the surveyors if they object to being observed while examination or treatment is being provided;

- If the RHC provides VNS, ask for a list of visits scheduled during the survey period. If visits are scheduled, explain that at least one visit will be observed;
- Explains that all interviews will be conducted privately with patients, staff, or visitors, unless requested otherwise by the interviewee;
- Discusses how the facility will provide the surveyor(s) in a timely manner access to a copy machine as well as access to clinical and other records, and other information as needed;
- Obtains the names, locations, and telephone numbers of key RHC staff and their responsibilities;
- Discusses the appropriate time, location, and possible attendees of any meetings to be held during the survey; and
- Proposes a preliminary date and time for the Exit conference.

During the entrance conference, the single surveyor or Team Coordinator arranges with the RHC's Administrator, or available administrative supervisory staff in his/her absence, to obtain the following:

- A list of all patients scheduled for that day. The list should include, at a minimum, the date, each patient's name, purpose of office visit, and the physician/mid-level furnishing the office visit. The surveyor or Team Coordinator indicates that a surveyor will be following the progression of at least one patient, selected by the surveyor from the list, through the office visit, so it is essential that information on the patients be provided as soon as possible, including the expected time between registration and being seen by medical staff.
- A list of:
 - All office visits from the past six months. In the case of a complaint survey concerning an office visit that took place further in the past, be sure to request a list that includes the month of the complaint case;
 - All cases in the past year, if any, where the patient was transferred from the RHC to another health care facility for emergency services;

The list should include, at a minimum, the date, each patient's name, purpose of office visit, and the physician/mid-level furnishing the office visit. The surveyor or Team Coordinator explains to the RHC that, in order to complete the survey within the allotted time, it is important the surveyor(s) is given this information as soon as possible. The RHC should begin compiling this list as soon as the entrance

conference concludes. Generally an RHC should be able to provide this information within an hour of the request.

- A location (e.g., conference room, an office not in use) where the surveyor(s) may meet privately during the survey, and also conduct patient record reviews, interviews, etc.;
- Access to a copy machine;
- A list including the names of the Medical Director, active Medical Staff, Allied Health professionals, and all other staff providing patient care;
- A copy of the facility's organizational chart;
- Specific written policies and procedures, upon request from the surveyor;
- Selected RHC personnel records identified by the surveyor;
- Written documentation related to the RHC's program evaluation or QAPI for ongoing self-assessment of quality;
- A list of services provided through agreement or arrangements; and
- A copy of the facility's floor plan.

For recertification or representative sample validation surveys, arrange an interview with the administrative staff member who will be providing information to complete the Form CMS-29 Verification of Clinic Data for Rural Health Clinic Program. SA may not require a certified RHC to submit an updated Form CMS-29 in advance of recertification. However, in the case of relocation of an RHC, the RHC must submit an updated Form CMS-29 to the SA at the same time it submits an updated Form CMS-855A to the Medicare Administrative Contractor (MAC.)

Task 3 – Information Gathering/Investigation

General Objective

The objective of this task is to determine the RHC's compliance with the CfCs through observations, interviews, and document review.

During the Survey

- Surveyors should always maintain a professional and calm demeanor;

- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyor(s) during a survey. However, maintaining open and ongoing dialogue with the facility staff throughout the survey process generally enhances the efficiency and effectiveness of the survey. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey.
- Surveyors need to respect patient privacy at all times during the survey.
- Surveyors are not permitted to conduct clinical examinations or provide clinical services to any of the RHC's patients. Surveyors may direct the attention of the RHC staff to address an immediate and significant concern affecting a patient's care.
- The surveyor should be aware of all significant issues or significant adverse events, particularly those that a surveyor believes may constitute an immediate jeopardy. Immediate jeopardy is defined as a situation in which the RHC's noncompliance with one or more CfCs has caused, or is likely to cause, serious injury, harm, impairment or death to a patient. If the surveyor believes, and, when applicable, the Team Coordinator agrees, that there is an immediate jeopardy situation, the guidance in Appendix Q of the SOM is followed.
- Informal discussions with facility staff may be held while the survey is ongoing in order to inform them of preliminary survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues.
- When more than one surveyor is on-site, the survey team should meet at least once daily in order to assess the status of the survey, progress on completion of assigned tasks, and areas of concern, as well as to identify areas for additional investigation. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues.
- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided upon request to the RHC, the surveyor is not a consultant and may not provide technical advice or consulting services to the RHC.

Observations

Observations provide direct knowledge of the RHC's practices, which the surveyor(s) must compare to the regulatory requirements in order to determine whether the RHC is in compliance. The interpretive guidelines for each of the CfCs provide detailed guidance

as to what the regulations require, as well as tips for surveyor activities to determine compliance.

Patient Care Observation

The surveyor, or Team Coordinator when applicable, should make it a priority at the beginning of the survey to select one or two patients scheduled to receive patient care services during the survey to observe. In addition to observing onsite patient care, if an existing RHC which has been identified by CMS RO as eligible to provide VNS has a scheduled VNS visit(s), the surveyor will also observe patient care services provided during the VNS visit. AOs may contact the appropriate CMS RO to ascertain whether or not an existing RHC has been approved to provide VNS. It is preferable to observe a patient on the first day of the survey, if a two day survey is scheduled, in order to get a more accurate picture of the RHC's routine practices. The number of patients selected will depend on the size of the RHC, as well as the size of the survey team and/or the scheduled length of the survey.

The surveyor(s) should observe various types of patient care services to look for evidence of compliance related to the various CfCs, e.g., physical plant and environment, provision of services and patient health records.

RHC Tour

The tour of the RHC may be accomplished while RHC staff is assembling the information requested during the entrance conference. The purpose of the tour is to get an overview of the whole RHC and to begin making findings about its compliance with the CfCs governing an RHC's physical plant and environment, 42 CFR § 491.6. The amount of time spent on the tour will depend on the size of the RHC. For revisit surveys, a tour is generally not necessary, although observations in various parts of the RHC related to the areas of prior noncompliance will be required.

Observation Methods

Observations provide direct knowledge of the RHC's practices, which the surveyor must compare to the regulatory requirements in order to determine whether the RHC is in compliance with the requirements. The interpretive guidelines for each of the CfCs provide detailed guidance as to what the regulations require, as well as tips for surveyor activities to determine compliance.

In general, when making observations, surveyors should assess general conditions such as:

- Building structure and layout, general appearance and cleanliness, smells;
- Staff-patient interactions, both clinical and non-clinical: for example, at what point are patients allowed into the facility? What happens to patients from the time they arrive to the time they leave? Is care provided by appropriate, qualified staff?

- Other staff activities: for example, how is clinical staff supervised? How are clinical records protected? Are infection control precautions observed?

A surveyor must take detailed notes of all observations, identifying the applicable regulatory standard(s). One set of observations might support findings related to multiple standards. Surveyors may find it convenient to use interpretive guidance “tag” numbers as a shortcut for identifying the applicable standards, but must always recall that tags are just a filing/sorting device, and that the regulatory authority is always based on the specific regulatory language.

Surveyors must attempt to obtain further verification of the factual accuracy of their observations from the patient, family, facility staff, or other team member(s), or by another mechanism. For example, when finding an outdated medication, surveyors can ask a member of the RHC’s professional staff to verify the drug’s expiration date.

Surveyors must introduce themselves to the patient and/or the patient’s representative prior to seeking permission to observe the delivery of care to that patient. The privacy and dignity of the patient must always be respected, along with the patient’s right to refuse to allow the surveyor to observe his/her care. However, an RHC does not have the right to prohibit/refuse any and all case observation by surveyors.

For each observation, the surveyor should document:

- The date and time of the observation(s);
- Location within the RHC;
- Patient and staff identifiers; a key containing identifiable information for patients must be kept on an identifier list separate from that of the staff identifiers. Do not use names, medical record numbers, Social Security numbers, or billing record numbers to identify patients, or names or positions for staff members;
- Individuals present during the observation;
- Activity/area being observed (e.g., observation of injection practices for adherence to accepted standards of infection control, observation of handling of samples for required laboratory services, etc.).

Document Review

RHCs maintain a variety of documents that provide evidence of their compliance/non-compliance with the regulations. Review of documents is a key component of the survey, but it is important to note that it must always be supplemented by surveyor observations and interviews. For example, it is not an efficient or effective use of surveyor time to

request a copy of all RHC policies and procedures for review; instead, it is preferable to make selective requests for such documents when observations or interviews suggest noncompliance in an area, in order to determine whether the problems stem from inappropriate policies and procedures, or failure to follow appropriate policies and procedures.

While it is importance to verify specific policies and procedures are in place as required by 491.7 and 491.9, it is never sufficient to determine compliance by just verifying that an RHC has an appropriate written policy and procedure in place. Surveyors must use a variety of means, including review of other documents, such as medical records, personnel files, maintenance records, etc., to confirm that the RHC actually follows its policies and procedures in its daily operations. Documents reviewed may be written or electronic, or a mixture of both, and may include the following:

- Clinical records (see discussion below);
- Personnel files to determine if staff members meet educational and training requirements, and are licensed or credentialed, if required. The RHC must comply with all Medicare requirements and State law governing scope of practice, as well as follow its own written policies for clinical staff responsibilities;
- Policy and procedure manuals or portions thereof. When reviewing policy and procedure manuals, verify with the RHC's leadership that they are current;
- Contracts or written agreements for services provided through agreements or arrangements. Review to verify these are current.

Copies of Documents

Surveyors must be able to make copies of all documents needed to support deficiency findings, whether by photocopying paper records or printing out pertinent portions of electronic health records (EHR). In the case of paper documents, the surveyor needs access to a photocopier in the RHC in order to make photocopies. Generally surveyors must not rely upon RHC staff to make photocopies for them. However, if the RHC insists that one of its staff members must operate the copier, then a surveyor must observe the copying process, in order to assure that changes or omissions do not occur. If requested by the RHC, the surveyor must make the facility a copy of all items the surveyor photocopies. All copies need to be dated and timed by the surveyor as to when photocopied, and identified, such as "RHC Patient Care Polices Requirements" – 10-25-09, or "Patient Record #1 - 10-25-09."

In the case of an RHC with an EHR system, CMS recommends that RHC surveyors not seek direct access to the EHR system, but instead have an RHC staff member operate the system to pull up any record information the surveyor requires, and to print out materials as requested by the surveyor. All copies need to be dated and timed by the surveyor as to

when printed, and identified, such as “RHC Patient Care Policies Requirements” – 10-25-09, or “Patient Record #1 - 10-25-09.”

Clinical Record Review

Active Patient Record Sample Size and Selection

After the RHC provides a log or some other record of active medical records from the previous 60-90 days, the team/surveyor will select a sample of medical records to review.

Clinical Record Sampling for Standard (Full) Surveys

It is generally preferred that the clinical record sample consist of records for RHC patients seen by a physician or non-physician RHC practitioner within the previous 90 days. At a minimum, the sample should be at least 20 records for an RHC with a monthly case volume exceeding 50. For lower volume RHCs at least 10 records should be selected. The sample size may be expanded as needed in order to determine compliance with the RHC CfCs, at the surveyor or Team Coordinator’s discretion. For initial surveys, the surveyor or Team Coordinator determines if there are enough medical records for surveyors to determine whether the RHC can demonstrate compliance with all of the CfCs.

The sample must include Medicare beneficiaries as well as other patients. Any emergency transfers to hospitals or Critical Access Hospitals (CAHs) should also be included.

Sampling for Complaint Surveys

CMS always assesses an RHC for its current compliance with the CfCs. For a complaint investigation, it is expected that the CfC(s) related to the complaint are evaluated in the same manner as they would be during a full or standard survey. Thus, it is **not** sufficient to look only at the clinical record for the complaint case in conducting a complaint survey.

The SA - or the RO, in the case of a deemed status RHC - will determine in advance of the survey which CfCs the surveyor(s) will be evaluating in relation to the complaint. Selection of the CfCs will be determined based on the nature of the allegation(s) explicitly stated or implied by the complaint – i.e., an allegation of transmission of an infectious disease will require review of the Physical Plant and Environment CfC, and probably also of the Program Evaluation CfC.

It will be necessary to review multiple clinical records, including the record of any patient identified in the complaint, and the selection of the sample to review will in part be dependent on the complaint allegations. Depending on the CfCs to be surveyed for a

complaint, as well as the date of service for any patient identified in the complaint, it may also be necessary to review older records.

A revisit survey may or may not require review of recent or older records, depending on the specific standards and conditions being re-evaluated.

Once the clinical records are available, the surveyor(s) can begin reviewing each record for evidence of compliance/noncompliance.

Give each clinical record observed/reviewed in the sample a unique identifier. A key containing identifiable information for patients must be kept on a separate identifier list. Do not use names, clinical record numbers, Social Security numbers, or billing record numbers to identify the patients or names or positions for staff. In reviewing the record, surveyors should confirm it contains items required by various CfCs, including but not limited to:

- Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and the instructions to the patient;
- Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;
- All practitioner's orders, reports of treatment and medications and other pertinent information necessary to monitor the patient's care;
- Signatures of the physician and other health care professional.
- Legible entries that are completed, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing or evaluating the service.

Interviews

Interviews provide another method to collect information, and to verify and validate information obtained through observations, record review and review of other documents. Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews:

- Prepare detailed notes of each interview conducted. Document the interview date, time, and location, the full name and title of the person interviewed, and key points made and topics discussed. To the extent possible, document quotes from the interviewee.
- Interviews with facility staff should be brief and to the point.

- Interviews should be used to determine whether staff is aware of and understand what they need to do for the RHC to comply with regulatory requirements, as well as the RHC's formal policies and procedures. It is not necessary for staff to be able to cite specific Medicare regulations, but they should be able to describe what they do in a way that lets surveyors determine compliance with the regulations.
- Be sure to interview staff having responsibilities related to each of the CfCs being surveyed.
- Use open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. For example, to determine if a staff member is aware of non-medical emergency procedures, and his/her role in such events, simply ask, "If you smelled smoke, what would you do?" Do not ask, "Does this RHC have policies and procedures to address non-medical emergencies?" Likewise, ask appropriate clinical staff, "Can you describe how a life-threatening/medical emergency is handled? Do not ask, "Does this RHC provide medical emergency procedures?"
- Surveyors must always introduce themselves and ask patients or their representatives for permission before they interview them. Surveyors must be sensitive when selecting patients for interview; for example, if a patient appears to be experiencing significant pain or anxiety, an interview request should not be made. The privacy, dignity and well-being of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to conduct an interview.
- Patient interview questions should focus on factual matters about which the patient is likely to have information. For example, ask "Did you notice whether the nurse or physician washed their hands or used a cleaning gel before providing care to you today?"
- Problems or concerns identified during a patient or family interview must be addressed in the staff interviews to gather additional information and to potentially validate the patient's perception.
- Validate as much of the information collected via interviews as possible, e.g., by asking the same question of several staff or patients, or by integrating interview responses with related surveyor observations or record review findings.
- If necessary, telephone interviews may be conducted but in-person interviews are preferred.

Task 4 – Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, and to review and analyze all information collected from observations, interviews, and record reviews. The surveyor's preliminary decision-making and analysis of findings assist in preparing the exit conference report.

Preparation

Prior to beginning this task, the surveyor must review his/her notes related to observations and interviews, as well as the documents he/she has photocopied (or printed out if the RHC uses an electronic health record system). The surveyor must be confident that he/she has everything needed to support his/her presentation of findings to the team, when applicable, and to his/her SA manager when preparing a formal survey report.

Discussion Meeting

A discussion meeting takes place when more than one surveyor participates in the onsite survey. A survey team should use this time to share their individual findings. The team must reach a consensus on all findings of noncompliance. Decisions about deficiencies must be team decisions with each member having input. During this meeting, the survey team will begin evaluating the formation/evidence found during the survey.

Information Evaluation

The surveyor(s) must evaluate the evidence and make decisions regarding compliance with each requirement. For initial, recertification, and validation surveys (if applicable), the surveyor should review the evidence gathered, proceeding sequentially through the regulatory requirements for each CfC to determine if the requirements are met. For complaint surveys, the surveyor should review the evidence related to each CfC selected for the investigation. All evidence that supports each finding of noncompliance must be documented. Any additional documentation or evidence needed to support identified noncompliance must be gathered prior to exiting the facility.

All noted noncompliance must be cited as a deficiency, even when corrected onsite during the survey.

When a noncompliant practice is determined to have taken place prior to the survey, this would be considered evidence of current non-compliance, **unless** there is documentation that the RHC identified the problem prior to the survey and implemented effective corrective action. In evaluating whether the RHC is currently in compliance, the surveyor(s) must consider:

- what corrective action the facility implemented and when it did this;

- whether the corrective action was sufficient to address the underlying causes of the deficiency;
- whether the corrective action was evaluated for its effectiveness to sustain long-term compliance; and
- whether there are any other findings from the survey indicating current non-compliance.

If the deficient practice was identified and corrected by the RHC prior to the survey and there is no other evidence of current non-compliance, this would be a case of past noncompliance and surveyors must not cite current noncompliance.

In the case of a revisit survey, the surveyor's task is to determine current compliance with the regulatory requirements that were cited as deficiencies during the previous survey. The surveyor should conduct observations, document reviews and interviews to assess current compliance with the CfC(s) addressed by the PoC.

Integrating Findings

The surveyor(s) integrates the findings derived from document review, observations, and interviews that pertain to each CfC surveyed, in order to make a determination of whether there is evidence of compliance/non-compliance.

Determining the Citation Level of Deficiencies

Citing noncompliance at the appropriate level, i.e., standard or condition-level, is critical to the integrity of the survey process.

The regulations at 42 CFR § 488.26(b) state in part, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a particular standard within the Conditions for Certification is noted, the determination of whether the lack of compliance is at the Standard or Condition level depends upon the nature of the noncompliance – i.e., how serious is the deficiency in terms of its potential or actual harm to patients - and the extent of noncompliance – e.g., how many different regulatory requirements within a CfC are being cited for noncompliance, or how widespread was a given noncompliant practice, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is sufficient to find condition-level noncompliance. Likewise, when an RHC has multiple standard-level deficiencies in a CfC, the extent of the non-compliance could be sufficient to find condition-level noncompliance.

Determinations of citation level for complaint surveys follow the same process that is applied to full surveys; the only difference is that the complaint survey itself is generally limited to the CfCs implicated in the complaint.

Gathering Additional Information

If additional information is required in order to determine facility compliance or noncompliance, the surveyor determines the best way to gather such information. If the survey was conducted by a survey team, the Team Coordinator makes the determination of whether additional information is required.

Task 5 - Exit Conference

General Objective

The general objective of this task is to informally communicate preliminary survey team findings and provide an opportunity for the exchange of information with the RHC's administrator, designee or other invited staff. The Exit Conference is both a courtesy to the RHC and a way to expedite the clinic's planning ahead of the formal receipt of the survey findings in the Form CMS-2567, Statement of Deficiencies. Additionally, an Exit Conference is not always guaranteed, as is noted in section 2724 of the SOM.

Prior to the Exit Conference

- The surveyor is responsible for organizing his/her presentation for and facilitating the exit conference.
- If the surveyor feels he/she may encounter a problem during the exit conference, he/she should contact the SA manager in advance to discuss the potential problems and appropriate methods to handle them.

If the survey is conducted by a survey team, the Team Coordinator would be responsible for the above tasks.

Discontinuation of an Exit Conference

CMS' general policy is to conduct an exit conference at the conclusion of all types of surveys as a courtesy to the provider/supplier and to promote timely remediation of quality of care for safety problems. However, there are some comparatively rare situations that justify refusal to conduct or continue an exit conference. For example:

- If the RHC is represented by an attorney (all participants in the exit conference, both surveyor(s) and RHC staff, must identify themselves prior to beginning the exit conference), surveyors may refuse to conduct the conference if the attorney attempts to turn it into an evidentiary hearing; or

- If the RHC staff /administration create an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, the surveyor(s) may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the surveyor stop the exit conference and call the SA for further direction. If a survey team is onsite, the Team Coordinator should take the above actions.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyor or Team Coordinator should select one of the tapes at the conclusion of the exit conference to take back to the SA. Videotaping is also permitted, if: 1) the surveyor/team agrees to this, and 2) a copy is provided the surveyor/team at the conclusion of the conference. The surveyor or survey team is under no obligation to consent to videotaping and is not required to offer a reason if it refuses to permit videotaping.

General Principles

The following general principles apply when conducting an exit conference:

- The RHC management determines which RHC staff will attend the exit conference.
- The identity of individual patients or staff members must not be revealed by surveyors when discussing the survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference or characterization by which identity may be deduced.
- Because of the information-gathering activities the surveyor or survey team has already engaged in, in most instances members of the RHC's staff should generally be aware prior to the exit conference of the areas, if any, where the survey team has concerns. Accordingly, there should be few cases where the RHC has not already had the opportunity prior to the exit conference to present additional information that might be relevant to the survey findings. The exit conference is not the correct setting for further information-gathering activities.

Exit Conference Sequence of Events

Introductory Remarks:

- Thank everyone for their cooperation during the survey.
- Reintroduce all surveyors who participated in the survey, even if they are no longer in the facility.

- Briefly reiterate what was the reason for the survey (i.e., initial, recertification, representative sample validation, or complaint).
- Explain how the exit conference will be conducted and any ground rules, such as,
 - the exit conference is an informal meeting for surveyors to summarize their preliminary findings;
 - brief comments on the findings may be made by the RHC, but the surveyor/team will not engage in a debate; or
 - whether comments will be permitted in the middle of a surveyor's presentation or only after the presentation has concluded;

Presentation of Findings

- The findings or information conveyed at the Exit Conference are preliminary in nature and are subject to change pursuant to the State and CMS supervisory review processes.
- Do not refer to any specific ASPEN tag numbers when describing deficiency findings as the tags numbers often identify the Condition or Standard-level classification for most non-long term care (LTC) deficiencies. Additionally, such specific details should wait supervisory review. This has been CMS' long-standing policy, and will continue for non-LTC providers and suppliers. In the process of completing the Form CMS-2567 after exiting the RHC, the SA will establish which tags/regulatory text to cite for each finding. It would be premature to make such statements during the exit conference.
- Present the findings of noncompliance, explaining why the findings indicate noncompliance with the regulatory requirement. If the RHC asks for the pertinent regulatory reference, provide the citation for the applicable CfC.
- Do not make any general characterizations about the survey results (e.g., "Overall the facility is very good." or "In general the facility is in compliance with Medicare requirements.") Stick to presenting the specific factual findings.
- Do not make any statements about whether the findings represent condition-level or standard-level deficiencies. Avoid statements such as, "the condition was not met" or "the standard was not met." It is better to state "the requirement related to XXX is not met."
- If an immediate jeopardy situation was identified during the review process that had not previously been discussed with the RHC's management, explain the significance and need for immediate removal of the IJ. Follow instructions in Appendix Q
- Do not rank findings. Treat CfC requirements as equally as possible.

- Ensure each deficiency finding is discussed at the exit conference.

Closure

- Explain the State and/or RO will sent the official survey findings presented in writing to the RHC via the Form CMS-2567, Statement of Deficiencies and PoC, which will be prepared and mailed to the RHC within 10 working days. The Form CMS-2567 documents for each regulatory requirement surveyed either that no deficiencies were found, or the specific deficiencies found. There will also be a letter communicating whether or not CMS will be taking enforcement action as a result of the survey's findings.
- If there are deficiencies and the RHC:
 - Does not have deemed status, advise the RHC that it will be required to submit a PoC for any deficiencies cited. Inform the RHC that a written PoC must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies, i.e., the Form CMS-2567.
 - Has deemed status, advise the RHC that it will be required to submit a PoC (also due within 10 calendar days of receipt of the Form CMS-2567) only if the statement of deficiencies indicates that there was condition-level noncompliance. The deemed status RHC may voluntarily submit a PoC even when there is only standard-level noncompliance, but the SA will not evaluate the PoC for its acceptability.
- When a PoC is required, the RHC's PoC and timeframes for implementation of corrective actions are incorporated into the Form CMS-2567 by the RHC and returned to the SA. Explain that the Form CMS-2567 is the document disclosed to the public about the facility's deficiencies and what is being done to remedy those deficiencies (Form CMS-2567 with PoC). Pursuant to 42 CFR 488.325, the Form CMS-2567 and an associated PoC can be made public 90 calendar days following completion of the survey and receipt by CMS of the SA's survey report, or whenever the PoC has also been received by the SA/RO, whichever comes first.
- Explain that, if a PoC is required, the RHC will have the following three options for each cited deficiency:
 - Accept the deficiencies stated on Form CMS-2567 and submit a PoC;
 - Record objections to the cited deficiencies on Form CMS-2567 **and** submit a PoC; or

- Record objections to cited deficiencies on Form CMS-2567, without submitting a PoC, but with written arguments and documented evidence that the deficiency findings are invalid.
- CMS will consider objections and accompanying documentation that attempt to refute the **factual** accuracy of the survey findings, but will not consider objections to CMS's judgment of the level, extent, scope or severity of a deficiency. CMS reviews additional documentation submitted by an RHC making an objection and, if the added evidence convincingly demonstrates the deficiency finding was factually inaccurate, will make a determination about removing the deficiency citation. In this instance, the SA will be asked to revise the CMS-2567.
- If CMS disagrees with the RHC's objections, the RHC must submit an acceptable PoC. Failure to submit an acceptable PoC or failure to correct a deficiency may result in termination of the RHC's supplier agreement in accordance with 42 CFR §§ 488.28(a) and 405.2404(b). See Section 2728 of the SOM for more detailed information on PoC requirements and timelines.

Explain that an acceptable PoC must contain the following:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will correct, and/or improve the processes that led to, the deficiency cited;
- The procedure for implementing the corrective actions;
- A completion date for correction of each deficiency cited;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the RHC into compliance, and that the RHC remains in compliance with the regulatory requirements;
- the title of the person responsible for implementing the acceptable PoC; and
- The administrator's signature and the date signed on page 1 of the Form CMS-2567;

Indicate that any required PoC will be reviewed by the SA, or in some cases, the RO, to determine whether it is acceptable. If a PoC is determined not to be acceptable, it will be returned to the RHC for revision.

State that in some cases, the SA will make an unannounced revisit survey to determine whether the RHC has come into compliance.

If the exit conference was audio- or videotaped, obtain a copy of the tape before exiting the facility.

All survey team members should leave the facility together immediately following the exit conference. If the facility staff provides further information for review, the surveyor, or team coordinator if applicable, determines the best way to review the additional information. It is usually prudent for at least two individuals to remain if all of the team members do not leave at the same time.

Task 6 – Post Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each SA and RO must follow the instructions in the SOM including:

- Timelines for completing each step of the process;
- Responsibilities for completing the Form CMS-2567, Statement of Deficiencies following the “Principles of Documentation;”
- Notification to the RHC regarding survey results, unless the RHC is a deemed status RHC, in which case the RO must review and concur with the Form CMS-2567;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the RO for further action/direction, such as concurrence with findings for deemed RHCs, authorization of a full survey for deemed RHCs with condition-level deficiencies);
- Compilation of documents for the supplier’s file;

NOTE: An RHC has deemed status only if CMS has certified it based on accreditation by a CMS-approved Medicare RHC accreditation program. Surveys of deemed status RHCs are only conducted if approved by the CMS RO.

Survey Package

If a survey team conducted the on-site survey, the Team Coordinator will assign responsibilities for completion of the various elements of the survey package.

Statement of Deficiencies Report & Plan of Correction

The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with Federal requirements. Also, it is the form that the RHC will use to submit a plan to achieve compliance. Form CMS-2567 is an official record and is available to the public on request.

There must be an indication on Form CMS-2567 whether any deficiency constitutes immediate jeopardy to a patient's health and safety.

Each deficiency statement must be written in terms specific enough to allow a reasonably knowledgeable person to understand what regulatory requirements were not met. The consequence for incorrectly or unclearly documenting deficiencies can be the inability of CMS to take needed enforcement action.

Surveyors must refrain from making clinical judgments. Instead, they must focus on the RHC regulatory requirements and how they were or were not met by the RHC.

After the surveyor(s) complete Form CMS-2567 in ASPEN, it must be submitted to a supervisor for review. If, after reviewing the form, the supervisor approves it, surveyors begin working on the remainder of the survey package. If the supervisor does not approve the form, then the surveyor must make any requested changes.

Other Survey Package Documentation

Complete the following documentation in hard copy. For complaint investigations, attach these materials to the corresponding complaint in the Aspen Complaint Tracking System (ACTS):

- Description of sample selection;
- Summary listing of sample cases;
- Summary of interviews;
- Complaint investigation narrative;
- Form CMS-29 – Verification of Clinic Data – Rural Health Clinic Program; and
- Form CMS-670, Survey Team Composition and Workload Report

Part II

Regulations and Interpretive Guidelines

J-0001

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.3 Certification procedures

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

Interpretive Guidelines § 491.3

Sections 405.2401 – 405.2404 establish the procedures for certifying a clinic as an RHC and recertifying existing RHCs, including issuing a Medicare agreement, and the conditions under which an RHC's participation in the Medicare program may be terminated. Section 405.2401(b) requires compliance with the Conditions for Certification (CfC) in 42 CFR Part 491 in order for an RHC to be certified.

Survey Procedures § 491.3

In general, there are no survey procedures specific to this Condition, with the exception of the provisions covered in the two standard-level tags below concerning provision of physician or visiting nurse services (VNS) outside the RHC.

With respect to the other requirements of Part 405, Subpart S, State Survey Agencies (SA) assess compliance with the remaining CfCs and make recommendations to the CMS Regional Office (RO). The RO determines whether to issue an initial RHC Medicare agreement or to terminate an existing RHC Medicare agreement, consistent with the requirements of 42 CFR Part 405 and as outlined in Chapter 2 of the State Operations Manual (SOM), sections 2240 - 2249.

J-0002

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Standard-Level Tag

§ 491.3 Certification procedures

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405....

§ 405.2412 Physicians' services.

Physicians' services are professional services that are furnished by either of the following:

(a) By a physician at the RHC . . .

(b) Outside of the RHC ... by a physician whose agreement with the RHC ... provides that he or she will be paid by the RHC ... for such services and certification and cost reporting requirements are met.

Interpretive Guidelines § 491.3 & § 405.2412

RHCs are permitted to provide their physician services outside the premises of the RHC, (i.e., a patient's home, a Part A SNF or at the scene of an accident, so long as there is a written agreement between the RHC and the physician. Note:

- Services provided inside a mobile RHC unit are considered to be provided inside the RHC; and
- A physician who provides RHC services is also free to provide physician services that are not RHC services outside the RHC; in this case the physician bills for those services separately rather than being reimbursed for them by the RHC.

The agreement between the RHC and a physician must specifically provide that the RHC pays the physician for the RHC services provided, and that the RHC will continue to meet Medicare certification and cost reporting requirements.

Survey Procedures § 491.3 & § 405.2412

- Ask the leadership of the RHC, and physician(s) at the RHC when applicable, whether or not physician services are ever provided outside the RHC facility. If yes, ask the RHC to see the written agreement(s) and determine whether it contains the required provisions governing payment, certification and Medicare cost reporting.

J-0003

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Standard-Level Tag

§ 491.3 Certification procedures

A rural health clinic will be certified for participation in Medicare in accordance with subpart X of 42 CFR part 405 . . .

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if the services meet all of the following:

- (1) The RHC . . . is located in an area in which the Secretary has determined that there is a shortage of home health agencies.**
- (2) The services are rendered to a homebound individual.**
- (3) The services are furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC . . .**
- (4) The services are furnished under a written plan of treatment that is both of the following:**
 - (i)(A) Established and reviewed at least every 60 days by a supervising physician of the RHC . . . ; or**
 - (B)(1) Established by a nurse practitioner, physician assistant or certified nurse midwife; and**
 - (2) Reviewed at least every 60 days by a supervising physician.**
 - (ii) Signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife of the RHC . . .**

(b) The nursing care covered by this section includes the following:

- (1) Services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved.**
- (2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.**

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, homebound means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, “place of residence” does not include a hospital or long term care facility.

§ 405.2417 Visiting nurse services: Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the RHC . . .

- (a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the RHC . . .**
- (b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency.**
- (c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.**

Interpretive Guidelines § 491.3 & § 405.2416 - §2417

RHCs are permitted to offer visiting nurse services (VNS) in patients' homes if they are located in an area with a shortage of home health agencies. To provide VNS, the RHC must apply to the SA, which performs an assessment in accordance with Section 2246 of the SOM. Based on this assessment the SA makes a recommendation to the CMS RO, and the RO makes the determination whether the RHC will be permitted to offer VNS.

If an RHC provides VNS, the SA must confirm that the services are being provided:

- by a registered nurse (RN) or a licensed practical nurse who is employed by or receives compensation from the RHC for providing such services;
- in accordance with a written plan of treatment which is:
 - established and signed by a supervising RHC physician, nurse practitioner, physician assistant, or certified nurse midwife;
 - reviewed and signed at least every 60 days by the supervising RHC physician; and
 - identifies the nursing and personal care services that are to be provided to the individual.

The VNS must be provided in the patient's home and must be documented in the RHC's clinical records, in accordance with the requirements at § 491.10.

Survey Procedures § 491.3 & § 405.2416 - §2417

- Review personnel files of staff making VNS visits, to ensure that they are currently licensed as either an RN or an LPN.
- Review a sample of records of patients receiving VNS to determine:

- Whether there is a written treatment plan for each patient, established and signed by an RHC physician or non-physician practitioner;
- Whether there is evidence that the plan was reviewed by an RHC physician at least every 60 days;
- Whether the clinical record documents the provision of VNS to the patient in accordance with the written plan for that patient.
- Observe at least one VNS visit, if any have been scheduled during the survey period, to determine whether care is being provided in accordance with the written treatment plan for that patient.

J-0010

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.4 Compliance with Federal, State and local laws

The rural health clinic . . . and its staff are in compliance with applicable Federal, State and local laws and regulations.

Interpretative Guidelines § 491.4

The RHC must ensure that it meets all applicable Federal, State and local law and regulations. Depending on the manner and degree of noncompliance with the standards contained in this Condition, condition-level noncompliance may be present and must be cited.

J-0011

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

Standard-level Tag**§ 491.4 Compliance with Federal, State and local laws**

The rural health clinic . . . and its staff are in compliance with applicable Federal, State and local laws and regulations.

Interpretative Guidelines § 491.4**Other Federal Requirements**

Neither CMS, nor State surveyors conducting surveys on its behalf, has the authority to interpret and enforce the laws and regulations of other Federal agencies. Further, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies. However, a surveyor who suspects an RHC may not be in compliance with other Federal requirements may refer the matter to the appropriate agency having jurisdiction. If CMS is notified of or becomes aware of another Federal agency's **final** enforcement action, citations under this regulation would be appropriate, but **only** if the

other agency's **final** enforcement action remains in effect and the violation of the other agency's regulations has not been corrected.

Survey Procedure § 491.4

Refer suspected noncompliance to the appropriate Federal agency having jurisdiction (e.g., blood-borne pathogens issues to the Occupational Safety and Health Agency; controlled drug accountability issues to the Drug Enforcement Agency; etc.)

J-0012

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.4(a) Licensure of clinic ...

The clinic . . . is licensed pursuant to applicable State and local law.

Interpretative Guidelines: § 491.4(a)

State licensure requirements generally exist for healthcare facilities. States may vary in their licensure requirements for entities that meet the Medicare definition of an RHC. Some States may not require licensure of these facilities at all, or may permit them to be licensed as part of another entity. In States where a separate facility license is required for a facility seeking to participate or already participating in Medicare as an RHC, the RHC must have a current license that has not expired or been suspended or revoked. The RHC must also be in compliance with all the State licensure requirements.

Neither CMS nor State surveyors conducting surveys on its behalf have the authority to interpret or enforce State licensure or other state laws. Failure of the RHC to meet State licensure law may be cited during the Federal survey only if the State has made a determination of noncompliance and has also taken a **final** enforcement action as a result. (Citation of licensure deficiencies on a State survey may represent an initial step rather than a final action or determination by the State licensure authority.) Additionally, the Federal survey of the RHC focuses on current compliance or non-compliance, not past noncompliance. Thus, for example, evidence that an RHC had received a State licensure citation in the previous year would not be grounds for citing the RHC for noncompliance with State licensure law, unless the State licensure authority has taken a **final** action and indicates the RHC is noncompliant at the time of the survey.

If as a result of a State citation of an RHC for deficiencies in its compliance with licensure requirements, the RHC has ceased operations and no longer furnishes services, it would be considered to have voluntarily terminated its Medicare agreement as of the last date on which it provided services to Medicare beneficiaries in accordance with § 405.2404(a)(3), which is cross-referenced in § 491.3 of the RHC CfCs). The SA must advise the RO of the RHC's cessation of business, and the RO will process a voluntary termination.

If at the time of the survey the RHC's State license has been revoked or suspended, then the RHC is not in compliance with this condition and must be cited for a condition-level deficiency. Furthermore, survey of the rest of the CfCs cannot be completed, since the

RHC is not providing medical services to patients. The SA must advise the RO of such revocation or suspension, and the RO will proceed with action to terminate the RHC's Medicare agreement in accordance with standard termination procedures.

If the surveyor identifies a situation that suggests the RHC may not be in compliance with State or local licensure laws, the information may be referred to the State licensure authority for follow-up.

Survey Procedures § 491.4(a)

- Prior to the survey, determine whether the RHC is subject to State or local licensure requirements.
- If applicable, verify that the RHC has a current state or local license – this may be done prior to the survey. If not verified independently prior to the survey, ask to see the RHC's license while on-site.
- If the surveyor identifies a situation that suggests the RHC may not be in compliance with any State or local licensure law, the information should be referred to the appropriate licensing authority for follow-up.

J-0013

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§ 491.4(b) Licensure, certification or registration of personnel.

Staff of the clinic . . . are licensed, certified or registered in accordance with applicable State and local laws.

Interpretative Guidelines § 491.4(b)

The laws requiring licensure vary from State to State. Examples of healthcare professionals that a state may require to be licensed could include: MD/DOs, dentists, physician assistants, nurse practitioners and nurses. Examples of personnel that a state might require to be certified or registered could include dietitians, technicians who administer diagnostic imaging procedures, pharmacy technicians, laboratory technicians, etc.

All RHC staff members that are required to be licensed, certified or registered by the State where the RHC is located must possess a current license, certification or registration, as applicable. It is the RHC's responsibility to ensure that all clinic personnel hold an appropriate and current license, certification or registration. There are considerable variations in the States' health care professional laws and regulations governing scope of practice acts relative to the extent to which physicians may delegate responsibilities to physician assistants, nurse practitioners and certified nurse-midwives. If a State requires a nurse practitioner or physician assistant to have all of their orders co-signed by a physician or establishes other requirements for supervision, the RHC must

ensure that its staff complies. In all cases, patient care must be provided by practitioners practicing within their permitted scope of practice under State law.

Survey Procedure § 491.4(b)

- Verify that RHC staff and personnel are licensed, certified, or registered, as applicable.
- Verify that the RHC has established, and follows procedures for determining that personnel are properly licensed, certified, and/or permitted.
- Verify that the RHC has established, and implements, policies and procedures to verify that personnel working at the RHC under contract or arrangement hold whatever license, registration, or certification is required under State law.
- Review a sample of personnel files of clinical staff to verify that licensure or other required credential information is present and up to date.

J-0020

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.5 Location of clinic.

Interpretative Guidelines § 491.5

Depending on the manner and degree of noncompliance with the standards of this condition, condition-level noncompliance may be cited.

J-0021

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.5(a) Basic requirements.

(1) An RHC is located in a rural area that is designated as a shortage area.

§ 491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

§ 491.5(c) Criteria for designation of rural areas.

(1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

(2) Excluded from the rural area classification are:

- (i) Central cities of 50,000 inhabitants or more;**
- (ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;**
- (iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.**

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

§ 491.5(d) Criteria for designation of shortage areas.

(1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

- (i) The ratio of primary care physicians practicing within the area to the resident population;**
- (ii) The infant mortality rate;**
- (iii) The percent of the population 65 years of age or older; and**
- (iv) The percent of the population with a family income below the poverty level.**

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

- (i) The area served is a rational area for the delivery of primary medical care services;**
- (ii) The ratio of primary care physicians practicing within the area to the resident population; and**
- (iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.**

Interpretative Guidelines § 491.5(a)(1), § 491.5(c) & § 491.5(d)

Only the CMS RO may make a determination as to whether an existing or prospective RHC is located in a rural area that is also designated as a shortage area. The RO relies upon information from:

- The US Census Bureau as to whether a location is in a rural area; and
- The Health Services and Resources Administration (HRSA) as to whether a location is in a designated shortage area.

See Sections 2240 - 2242 of the SOM for more information about how the RO makes determinations as to whether an RHC meets the location requirements. The SAs may conduct preliminary assessments of the eligibility of an initial applicant for certification as an RHC, in order to avoid conducting a survey of a potentially ineligible applicant. If the SA suspects an applicant's location is not eligible, it advises the RO promptly, so that the RO can make a determination. Should this situation occur, the SA should **not** conduct a survey of the applicant unless the RO advises that it has found the applicant's location to meet the location requirements.

Survey Procedure § 491.5(a)(1), § 491.5(c) & § 491.5(d)

- Prior to conducting an initial on-site survey, make a preliminary assessment as to whether the RHC applicant meets the basic location requirements by reviewing the Form CMS-29 Verification of Clinic Data – Rural Health Clinic Program.
- Verify, once on-site, that the location listed on the Form CMS-29 is the same as the location where services are actually being provided.

J-0022

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[Basic requirements]

§ 491.5(a)(3) . . . the RHC . . . may be permanent or mobile units.

- (i) Permanent unit.** The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic . . . are housed in permanent structure.
- (ii) Mobile unit.** The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic . . . are housed in a mobile structure, which has fixed, scheduled location(s).

Interpretative Guidelines § 491.5(a)(3)(i)-(ii)

An RHC may be housed in:

- a fixed, permanent structure;
- a mobile unit; or
- a permanent structure which also provides RHC services in one or more mobile units.

In all cases, each structure or unit must contain within it all the objects, equipment, and supplies required by the RHC for the clinical services that it furnishes.

Mobile Unit

An RHC that consists only of a mobile unit must comply with all of the CfCs in that unit, including the location requirements. All mobile units, regardless of whether they are the entire RHC or a part of an RHC that also has a permanent structure, must have a fixed set of locations in which the unit is scheduled to be providing services at specified dates and times, and each unit must adhere to this schedule. For new applicants, the mobile locations in which services are provided must meet the rural and shortage area requirements at the time of survey. For existing RHCs, if services are being provided at locations other than its original locations, the new locations must meet the rural and shortage area requirements at the time of survey. This does not mean that the RHC is not able to periodically change the schedule for its mobile services. Instead, it means that the mobile unit must operate at locations that meet the location requirements and those locations and times are documented by the RHC and made available to the public in advance of scheduled operations, so that patients can know when and where services will be available to them. The schedule of times and locations must be posted on the mobile unit but must also be publicized by other means that patients could consult in advance, e.g., on a website, in local libraries or stores, etc.

Survey Procedures § 491.5(a)(3)(i)-(ii)

- Determine whether the RHC has available in its permanent structure or mobile unit all of the objects, equipment, and supplies required for the provision of RHC clinical services.
- If the RHC is a mobile unit, or has a mobile unit in addition to its permanent structure, determine whether it has a publicly available schedule for the upcoming times and locations of mobile RHC services. Determine whether the RHC has posted schedules on the unit as well as provided public notice by other means.
- Determine whether the mobile location(s) meet the rural and shortage locations requirements.

J-0023

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[Basic requirements]

§ 491.5(a)(3) . . . the RHC . . . may be permanent or mobile units.

- (iii) **Permanent unit in more than one location.** If clinic . . . services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic . . .

Interpretive Guidelines § 491.5(a)(3)(iii)

A Medicare-certified RHC is not permitted to have more than one permanent unit, i.e., it may not operate out of permanent structures in more than one location. Location is identified as the physical address where medical services are provided. If an organization owns several facilities operating out of permanent units at different locations; that it seeks to enroll in Medicare in order to provide RHC services in each facility, it must enroll each permanent unit separately, and each must independently and fully comply with the RHC CfCs. If one RHC occupies several suites within the same building, sharing the same address, it is considered to have only one permanent unit. It is also possible for separate RHCs to occupy different suites in the same building; when this occurs, each RHC must independently meet the RHC CfCs, and cannot co-mingle their services.

Survey Procedures § 491.5(a)(3)(iii)

- If the RHC has a webpage, check to see if the RHC holds itself out to the public as having multiple permanent locations.
- Ask RHC staff members whether the RHC has any other locations, other than mobile units.

J-0024

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.5(b) Exceptions.

(1) CMS does **not** disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

Interpretative Guidelines § 491.5(b)(1) - § 491.5(b)(3)

Loss of Location Eligibility

A provider or supplier is expected to be in substantial compliance with its applicable conditions at all times. This applies to conditions which establish facility location requirements as well. But for RHCs, there is a grandfathering provision that permits an existing certified RHC to remain an RHC even if population growth and/or changes in the availability of health care practitioners results in their no longer meeting the location requirements at § 491.5(a)(1).

CMS makes a presumption that every RHC seeks continued certification for participation in Medicare, including by application of this exception when necessary, unless the RHC has notified CMS of a voluntary termination of its RHC agreement. As a result, there is no special procedure for the RHC to file a request for exception to the location requirements and there is no new determination by the CMS RO concerning a certified RHC's ongoing compliance with the location requirements when the SA conducts a full RHC survey, regardless of whether the survey is conducted for periodic recertification of the RHC, as a representative sample validation survey, or for any other purpose. Although the grandfathering provision means that CMS does not terminate a certified RHC's Medicare agreement due to its location no longer meeting the rural or shortage area location requirements, CMS does continue to collect RHC location data. SAs conducting full surveys must still collect this and other data specified on the Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program. The information collected is updated in the Automated Survey Process Environment (ASPEN) which may be aggregated and used for future policy analysis.

If an existing RHC relocates, the grandfathering provision does not apply and the RHC must meet both the rural and shortage area location requirements at the new location. As with initial RHC location determinations, the CMS RO is responsible for making the actual determination of compliance with the location requirements. Determinations are made only after the relocation has occurred, and the CMS-855A has been submitted by the RHC to the appropriate Medicare Administrative Contractor, and the Form CMS -29 has been submitted by the RHC to the SA. Although an onsite survey is not required, the CMS RO has the discretion to require a survey in individual cases to verify that services are being provided at the new location identified in the submitted documentation.

Facilities Operating on July 1, 1977

This provision applies to initial applicants for RHC certification and therefore is not likely to have any practical application at this time. The SA should consult with the CMS RO if it believes it has encountered a situation where this provision would apply.

J-0040

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.6 Physical plant and environment.

Depending on the manner and degree of noncompliance with the standards within this condition, there may be condition-level noncompliance.

J-0041

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.6(a) Construction:

The clinic . . . is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

Interpretative Guidelines § 491.6(a)

The RHC must ensure that the physical plant of its permanent and/or mobile unit is constructed, arranged in terms of its layout, and maintained in a manner to ensure patient access and safety of its patients and personnel. The clinic's layout and fixtures must not present hazards that increase risk of patient injury, such as slippery floors or torn carpets that may present tripping or fall hazards, or ceilings panels that are in danger of falling, etc. The physical plant also must be designed and constructed in accordance with applicable State and local building, fire, and safety codes, but surveyors conducting RHC surveys on behalf of CMS do not assess compliance with such State and local code requirements.

Further, the clinic must have enough space, for the fixtures, equipment and supplies required, in order for it to provide those RHC services which must be furnished directly, i.e., provided within the RHC rather than under arrangement. The clinic must also comply with applicable Federal, State and local laws and regulations and accepted standards of practice for primary care services when determining how much space it requires for its direct services.

Survey Procedures § 491.6(a)

- Observe whether the clinic's physical plant is well constructed and arranged, and does not present barriers to patient access or hazards to patient safety.
- Observe whether the clinic has sufficient space given for the type and scope of services provided and the number of patients served.

J-0042

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.6(b) Maintenance:

The clinic . . . has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

Interpretative Guidelines § 491.6(b)(1)

The RHC must have a preventive maintenance program which ensures all essential mechanical, electrical and patient-care equipment is maintained so that it operates safely. Essential mechanical, electrical and patient care equipment includes things such as heating, ventilation and air conditioning systems, electrical systems, plumbing systems, telephone systems, elevators, and any biomedical equipment the clinic uses. Biomedical equipment means devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the clinic, e.g., blood pressure monitors, re-usable diagnostic scopes, EKG machines, scales, laboratory equipment, etc.

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using qualified clinic personnel, contracted services, or through a combination of clinic personnel and contracted services. For example, clinics that rent space in buildings with other occupants generally would have a contractual agreement with the landlord for maintenance of essential building systems. Clinics may also contract for maintenance of their biomedical equipment. In all cases, clinics must follow or ensure that their contractors follow equipment manufacturers' recommended maintenance activities and schedules. Clinics must document their preventive maintenance activities. This documentation must be incorporated into the RHC's program evaluation plan.

Survey Procedures § 491.6(b)(1)

- Is there documentation that mechanical or electrical equipment is regularly inspected, tested and maintained in accordance with the manufacturer's recommendations?
- If documentation is missing, ask to see the clinic's policies and procedures for equipment maintenance, to determine whether the problem is with content of the policies and procedures, and or with failure to follow policies and procedures.
- Ask staff to provide a copy of or access to copies of the manufacturer's recommendations for mechanical or electrical equipment.
- Ask staff whether there have been any problems with equipment breakdowns or malfunctions. If yes, ask for maintenance documentation for the equipment in question

J-0043

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[The clinic . . . has a preventive maintenance program to ensure that:]**§ 491.6(b)(2) Drugs and biologicals are appropriately stored; and****Interpretative Guidelines § 491.6(b)(2)**

The RHC must ensure the appropriate storage of drugs and biologicals which are used in the clinic. Drugs and biologicals must be stored and maintained in accordance with the manufacturer's instructions for temperature and other environmental conditions as well as expiration dates, etc. They may not be stored in areas that are readily accessible to unauthorized individuals/personnel. The clinic's policies and procedures must identify which types of clinic staff are authorized access to drugs and biologicals. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are considered secure. If medications are kept in cabinets located in areas where patients, visitors or other unauthorized personnel have ready access when clinic personnel are not also present, the cabinets must be locked.

Survey Procedures § 491.6(b)(2)

- Verify drugs are stored according to manufacturer instructions.
- Verify that drugs are not accessible to unauthorized individuals/personnel.

J-0044

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[The clinic . . . has a preventive maintenance program to ensure that:]**§ 491.6(b)(3) The premises are clean and orderly.****Interpretative Guidelines § 491.6(b)(3)**

The RHC must provide and maintain a clean and orderly environment. All areas of the clinic must be clean. These areas include, but are not limited to, the waiting area(s), exam room(s), staff lunch room(s), rest room(s), and office space. The clinic must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and clean environment. Policies and procedures for an orderly and clean environment must address the following:

- Measures taken to maintain a clean and orderly environment during internal or external construction/renovation;
- Measures to prevent the spread of infectious diseases. At a minimum the following must be addressed:
 - Hand hygiene for staff having direct patient contact;
 - Safe injection practices;
 - Single-use devices, and, when applicable, high-level disinfection and sterilization;
 - Safe use of point-of-care devices;
 - Routine cleaning of environmental surfaces, carpeting, and furniture;
- Disposal of waste, including medical waste;
- Food sanitation, if employee food storage and eating areas are provided; and
- Pest control.

Survey Procedures § 491.6(b)(3)

- As a resource, applicable questions from **Part 2** of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM, may be used to assist with identifying the types of observations surveyors should make in an RHC with respect to hand hygiene, injection practices, and, when applicable, single-use devices, high-level disinfection and point-of-care devices. This form may be used to assist RHC surveyors; however, it is not a required RHC form.
- Observe whether all areas which patients use or in which they may receive clinic services are clean and orderly, including the waiting area(s), the exam room(s), office space, rest rooms, floors, horizontal surfaces, patient equipment, mechanical rooms, central supply, and storage areas, etc.

J-0060

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.7 Organizational structure.

Depending on the manner and degree of noncompliance identified for standards within this condition, there may be condition-level noncompliance.

J-0061

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§.491.7(a) Basic requirements.

(1) The clinic . . . is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(b) Disclosure. The clinic . . . discloses the names and addresses of: . . .

(3) The person responsible for medical direction.

§ 491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and

(2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations).

Interpretative Guideline §§ 491.7(a)(1) & 491.7(b)(3)

The clinic must be under the medical direction of a physician who is responsible for the quality and appropriateness of health care services furnished in the RHC. In light of the definition of a physician at § 491.2 and due to the supervisory and oversight responsibilities involved in providing medical direction, only an MD or DO may serve as the RHC's medical director. The MD or DO must hold a current license that is issued or recognized by the State in which the RHC is located. The nature of medical director's duties are specified at § 491.8(b). By contrast, the language of § 491.7(a)(1) is focused on the requirement for the RHC to have an individual who is explicitly charged with being the clinic's medical director. There must be documentation available in the RHC identifying the name, address, and phone number of the clinic's medical director.

Any change in the physician responsible for the clinic's medical direction requires immediate notification to the appropriate SA. When identifying a new physician responsible for medical direction, the RHC provides the SA with the name, address, and phone number of the new medical director and evidence that the physician is licensed to practice in the State in which the RHC is located. Such change in medical director does not require resurvey or recertification, if the change can otherwise be adequately verified.

There is no waiver available should the physician functioning as the medical director leave a clinic that is already certified as an RHC. However, CMS affords currently certified RHCs a reasonable time to come back into compliance with the physician medical director requirement if the RHC can provide documentation that it initiated good faith efforts **prior to the survey** to obtain the regular services of a physician medical director, as well as arrangements it has made for immediate temporary physician services to perform required physician responsibilities in accordance with § 491.8(b). This flexibility is not available to an applicant for initial RHC certification.

In this situation, the already-certified RHC must still be cited for violating § 491.7(a)(1), but there is discretion with respect to the length of time the RHC is allowed to implement a plan of correction. Since the RHC regulations permit the RHC physician medical director to carry out many of his/her responsibilities via telecommunications and to provide telemedicine services, generally an RHC should be able to secure the required physician services within a reasonable period of time. The SA must make a recommendation to the CMS RO on whether to provide an RHC an extended period of time to implement a PoC. The RHC must inform the SA of all actions taken to recruit a replacement and expected outcome.

NOTE: To ensure continuity of care, it is permissible to use a locum tenens (i.e., temporary) MD/DO as the medical director of the RHC, providing that same MD/DO is contractually bound to provide services to the clinic for a minimum of six months.

The clinic must also have a health care staff that meets the requirements of § 491.8. This portion of this standard is evaluated under § 491.8, but deficiencies cited under that provision may also be cited under § 491.7(a)(1)

Survey Procedures §§ 491.7(a)(1) & 491.7(b)(3)

- Verify that the clinic has documentation identifying the name and address of its medical director.
- Confirm that the individual identified in the documentation is an MD or DO and still practicing at the RHC.
- Confirm that the medical director holds a current license issued or recognized by the State where the clinic is located. Ask staff who the clinic's medical director is and confirm that the same individual is the one the RHC disclosed as its medical director.
- If an already certified RHC clinic has no permanent medical director at the time of the survey, ask for documentation of when the previous medical director ceased performing that function, and of the efforts the RHC has made to fulfill the requirement.

J-0062

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.7(a) Basic requirements.]

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

(b) Disclosure. The clinic . . . discloses the names and addresses of:

(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);

(2) The person principally responsible for directing the operations of the clinic . . .

Interpretative Guidelines § 491.7(a)(2) & § 491.7(b)(1)-(2)

The clinic must establish in writing the manner in which it is organized, including the person who is principally responsible for the day-to-day operations, the lines of authority between that individual and the owner(s) and between that individual and other staff of the RHC. The RHC must identify in writing all types of staff positions, their place in the organizational arrangement, and their functions and responsibilities. There must be a written record of the name and address of the person who is principally responsible for the day-to-day operations of the clinic and this information must be furnished to surveyors upon request.

With respect to the requirement for disclosure of the clinic's owners, the latest disclosure should be contained in the latest copy of the Form CMS-855A, Medicare Enrollment for Institutional Providers, which the clinic is required to file in order to enroll in the Medicare program and required to update if its information changes. The MAC provides the CMS RO and SA copies of updates to the Form CMS- 855A information it receives. Review of this information disclosure is handled primarily by the MAC. It is the responsibility of the RHC to file an updated Form CMS 855A with the MAC if there are changes to the information it previously submitted.

The Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program, which is used to collect clinic ownership information and clinic personnel data, is also completed. See Chapter 2 of the SOM, section 2200 for detailed instructions on completing the CMS-29.

The clinic must have written policies and procedures addressing both administrative and clinical activities. Requirements for patient care policies are specified at §491.9(b) and are not evaluated under § 491.7(a)(2). Administrative policies and procedures would address topics such as personnel, fiscal, purchasing, and building and equipment maintenance, as well as any other topics the clinic's management finds pertinent.

Survey Procedures § 491.7(a)(2) & § 491.7(b)(1)-(2)

- Ask the clinic to provide a copy of its organizational chart and any supporting documentation that articulates the lines of authority and responsibilities of clinic officers and personnel.
- Ask the clinic to identify the person who is principally responsible for day-to-day operations.

- Ask to see the clinic's current administrative and clinical policies. Do not review the content of these policies; just confirm that the clinic has written policies.
- Verify the clinic owner as captured on the CMS-29.
- Verify the names and addresses of the required disclosures are available in the RHCs written records.

J-0080

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.8 Staffing and Staff Responsibilities.

Depending on the manner and degree of noncompliance identified for standards within this condition, there may be condition-level noncompliance.

J-0081

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.8(a) Staffing.

(1) The clinic . . . has a health care staff that includes one or more physicians . . .

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic . . . , or under agreement with the clinic . . . to carry out the responsibilities required under this section.

§491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and

(2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations).

Interpretative Guidelines § 491.8(a)(1) & (2)

An RHC must, at a minimum, have a health care staff that includes one or more physicians; if the clinic has only one physician, that physician must be either an MD or a DO in order to perform the responsibilities of the clinic's medical director. The physician must hold a current license issued or recognized by the State in which the RHC is located.

The physician(s) may be the clinic's owner (who may also be an employee of the clinic at the same time), an employee of the clinic, or providing services to the clinic under a contractual arrangement. CMS interprets an "employee" to be an individual to whom the clinic issues an IRS Form W2, Tax and Wage Statement (See 79 FR 25462, May 2, 2014). If the physician is not responsible for medical supervision nor the medical direction of the clinic, contractual arrangements may either be directly between the clinic and an individual physician, or between the clinic and a third-party entity that supplies the clinic with physician services, such as a locum tenens agency.

In all cases the RHC must have sufficient practitioners, both physician and non-physician, to furnish the volume of RHC services it provides to its patients, consistent with accepted standards of practice.

Survey Procedures § 491.8(a)(1) & (2)

- Confirm that the clinic has at least one physician who is providing physician services. Confirm that the physician has a current license issued or recognized by the State in which the RHC is located.

J-0082

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.8(a) Staffing.]

(1) . . . Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(3) The physician assistant, nurse practitioner, . . . may be the owner or an employee of the clinic . . ., or may furnish services under contract to the clinic . . . In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

§491.2 Definitions. As used in this subpart, unless the context indicates otherwise: . . .

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

- (1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or**
- (2) Has satisfactorily completed a formal 1 academic year educational program that:**
 - (i) Prepares registered nurses to perform an expanded role in the delivery of primary care;**
 - (ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and**
 - (iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or**
- (3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart . . .**

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

- (1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or**
- (2) Has satisfactorily completed a program for preparing physician's assistants that:**
 - (i) Was at least 1 academic year in length;**
 - (ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and**
 - (iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or**
- (3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.**

Interpretative Guidelines § 491.8(a)(1) & (3)

In addition to having a physician on staff, the RHC's health care staff must also include one or more nurse practitioner(s) (NP) or physician assistant(s) (PA), as defined at § 491.2. The RHC's NP and/or PA must meet the Medicare definition of an NP or PA and be licensed in accordance with the law of the State in which the RHC is located and practicing within their permitted State scope of practice.

At least one NP or PA must be an employee of the RHC (note that a clinic's owner may also be an employee; this is at the owner's discretion). CMS interprets an "employee" to mean an individual to whom the clinic issues an IRS Form W-2, Wage and Tax Statement. (See 79 FR 25462, May 2, 2014) However, once the clinic has employed at least one NP or PA, the other practitioners may furnish services under contract to the clinic instead of being employees. These other NPs or PAs may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

In all cases the RHC must have sufficient practitioners, both physician and non-physician, to furnish the volume of RHC services it provides to its patients, consistent with accepted standards of practice.

- As provided by § 1861(aa)(7) of the Act, and implemented in Section 2248 of the SOM, an existing RHC may request a waiver of the requirement to employ a NP or PA. The mid-level staffing waiver is applicable to Medicare-participating RHCs only. Initial applicants to participate in Medicare as an RHC are **not** eligible for staffing waivers. CMS grants a currently certified RHC a one-year waiver of the requirement to employ a NP or PA if:
- The RHC submits the written request for a waiver to the appropriate SA;
- The RHC demonstrates that it has been unable, despite reasonable efforts, to hire a NP or PA in the previous 90-day period; and
- The RHC's request is submitted six months or more after the date of the expiration of any previous such waiver for the RHC.

The SA is responsible for reviewing the evidence the RHC provides regarding its efforts to hire an NP or PA in the previous 90 days and recommending approval or disapproval of the requested waiver to the RO. The SA must complete its review and recommendation within 30 calendar days of receiving the written waiver request from the RHC.

The waiver is deemed to have been granted, unless the waiver request is denied by the RO within 60 calendar days after the date the SA received the RHC's waiver request. In cases where the waiver request is deemed to have been approved, the effective date of the 1-year waiver is the 61st day after the date the request was received by the SA.

See Section 2248 for more details on the waiver process and the expectations for RHCs and SAs

Survey Procedures § 491.8(a)(1) & (3)

- Determine that the clinic has at the time of the survey at least one NP or PA who is an employee of the clinic, as evidenced by the clinic issuing a W-2.
- If the clinic already participates in Medicare as an RHC and does not employ a NP or PA, check whether there is a valid waiver in effect.

J-0083

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.8(a) Staffing.]

(3) The . . . nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic . . .

Interpretative Guidelines § 491.8(a)(3)

The clinic is not required to have a nurse-midwife, clinical social worker or clinical psychologist on staff. If it does have any of these on staff, they must be licensed as required by State law of the State in which the clinic is located, and must be practicing within their permitted scope of practice.

A nurse midwife, clinical social worker or clinical psychologist who is on the clinic's staff may be the clinic's owner (who may also be an employee at the same time), an employee of the clinic, or providing services to the clinic under a contractual agreement. These types of practitioners may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

Survey Procedures § 491.8(a)(3)

- If the clinic has a nurse midwife, clinical social worker, or clinical psychologist on staff, verify that the individual has a current State license when one is required under State law.

J-0084

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[§ 491.8(a) Staffing.]

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

Interpretative Guidelines § 491.8(a)(4)

The clinic's staff may include personnel who are not practitioners but who provide clinical services, for example, registered nurses, licensed practical nurses, laboratory technicians, etc. In all cases personnel must hold current State licenses when required. All such personnel must be supervised at all times by a practitioner, either a physician or a non-physician practitioner, on the RHC's professional healthcare staff. Supervisory responsibilities may be shared among practitioners. For example, an NP on the RHC's staff may be the official supervisor who conducts regular performance reviews, but when that NP is not on duty, the RHC's physician or another NP or other non-physician practitioner may provide supervision.

Survey Process § 491.8(a)(4)

- Determine whether all clinical staff members who are not practitioners have a current State license or certification, as required.
- Ask clinical staff members who are not practitioners to identify their supervisor(s).
- Is there someone responsible for supervising non-practitioners on the clinical staff at all times the RHC is providing services? Request the name of that individual. Interview other clinical staff to confirm.

J-0085

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[§ 491.8(a) Staffing.]

(5) The staff is sufficient to provide the services essential to the operation of the clinic . . .

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic . . . operates. . . .

Interpretative Guidelines § 491.8(a)(5) & (6)

The clinic must be sufficiently staffed to provide the services offered by the RHC. Specifically, this means that the clinic has sufficient staff practicing within their permitted scope of practice to provide RHC services to the clinic's patients at all hours that the clinic is open and operating. Consistent with § 491.9(c), the RHC services the clinic furnishes are diagnostic and therapeutic services and supplies similar to those furnished in a physician office, including, but not limited to, performing history and

physical examinations, assessment of health status, and treatment for a variety of medical conditions. The clinic must also furnish specified laboratory services and first responder-type emergency services to individuals in the clinic experiencing a medical emergency. The clinic must have sufficient staff members who are qualified to furnish these services to the volume of patients the RHC sees. Even when staffing meets the minimum requirement in terms of practitioner time at the RHC, the staffing may be insufficient for the volume of services the RHC provides.

The clinic may only be open and furnishing RHC services if there is a physician, NP, PA, certified nurse midwife, clinical social worker, or clinical psychologist on site and available to furnish services. Although the physician medical director may perform many, not all, of his/her responsibilities remotely via telecommunications, this does not mean the clinic can be open and furnishing services without any practitioner on-site. With the exception of services the clinic's medical director or other MDs or DOs may provide by telemedicine, the clinic may only furnish those services that are within the scope of practice of the practitioners who are on site at the time the services are offered. The loss of a PA or NP staff member may require the RHC to request a temporary staffing waiver via its SA. It may also require a temporary adjustment of the clinic's operating hours or services and an adjustment in visits by the physician(s) providing medical direction. It is the responsibility of the clinic to promptly advise the SA of any changes in staffing which would affect its certification status.

(NOTE: See the guidance for § 491.8(a)(3) and Section 2248 for more details on the waiver process and the expectations for RHCs and SAs.)

RHCs may allow beneficiary entry to the waiting room or other non-patient care areas to handle billing inquiries or to get out of the weather when the mid-level practitioner as defined in §493.2, clinical social worker, clinical psychologist or physician staff member is not present to provide health care services. However, the clinic is not considered to be in operation as an RHC during this period. No health care services may be provided until a mid-level practitioner, clinical social worker, clinical psychologist or physician staff member is present onsite. There should be a reasonable timeframe between administrative transactions conducted on the premises outside the hours of operation of the RHC and the commencement of RHC operations with the healthcare professional's arrival. Any RHC that choose to exercise this flexibility should post the hours of administrative services only versus the hours of RHC operations. Signage should clearly delineate times the healthcare professional staff member is present onsite. If State law does not allow access to the RHC premises when the clinic is not in operation as an RHC, the facility must adhere to such laws.

Survey Procedures § 491.8(a)(5)& (6)

- Determine whether there is a physician or a non-physician practitioner on-site at all times the RHC is open. Review staff schedules and the clinic's hours of operation to confirm. Ask staff members if the RHC is ever open and providing services when no practitioner is present.

- Verify posted hours to confirm appropriate professional healthcare staffing within the RHC's hours of operation.

J-0086

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[§ 491.8(a) Staffing.]

(6) . . . for RHCs, a nurse practitioner, physician assistant or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

Interpretative Guidelines § 491.8(a)(6)

A NP, PA or certified nurse-midwife (CNM) must be available to furnish patient care services at least 50 percent of the operating hours during which RHC services are offered, even when a physician is also present in the clinic. All time that a NP, PA or certified nurse-midwife (CNM) is present in the clinic during the clinic's operating hours, even if not actually providing RHC services to patients, may be counted toward the 50 percent requirement. In addition, when RHC services are furnished to clinic patients outside of the clinic (e.g. in the patient's home, in a SNF, or in another residential facility), the time spent providing RHC services outside the clinic (excluding travel time) may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a NP, PA, CNM, CSW nor a CP is available on-site, a physician must be available on-site to provide needed services in order for the RHC to be open and operating. With the exception of services the clinic's medical director or other MDs or DOs may provide via telemedicine, the clinic may only furnish those services that are within the scope of practice of the practitioner(s) who are on site at the time the services are offered".

The following are some examples of how determinations regarding the 50 percent requirement may be made:

A clinic offers RHC services from 10 a.m. to 5 p.m. Tuesday through Friday, for a total of 28 hours per week. A physician, NP, PA, CNM, clinical social worker, or clinical psychologist must be available to furnish patient care services, within their permitted scope of practice, during all 28 service hours. In addition, a NP, PA, or CNM must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence for at least 14 hours (50 percent of the 28 service hours) for the RHC to furnish patient care services.

Note: If the NP, PA or CNM are not providing RHC services on-site, the physician must be available on-site.

In some cases, the clinic's weekly schedule may not be a reasonable period of time on which to base these determinations, and consideration of a biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when the clinic's schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 a.m. to 4 p.m., and one Friday a month from 10 a.m. to 4 p.m., for a total of 18 hours per month. Of these 18 hours, a NP, PA, or CNM must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 50 percent of that time (9 hours) for the RHC to furnish patient care services. This requirement would be met if a NP, PA, or CNM was on-site on one Tuesday for 3 hours and on the Friday for 6 hours, or through some other schedule that results in their availability 9 hours/month.

As provided by § 1861(aa)(7)(A) of the Act, and implemented in Section 2248 of the SOM, RHCs may request a waiver of the requirement that a NP, PA or CNM be available to furnish patient care services at least 50 percent of the time the RHC operates. The waiver is applicable to Medicare-participating RHCs only. Initial applicants requesting to participate in Medicare as an RHC are **not** eligible for mid-level staffing waivers. CMS grants a currently certified RHC a one-year waiver of the NP/PA/CNM staffing requirement if:

- The RHC submits to the SA a written request for a waiver;
- The RHC demonstrates that it has been unable, despite reasonable efforts, to arrange to have either a NP, PA, or CNM on duty at least 50 percent of the time the RHC operates in the previous 90-day period.
- The RHC's request is submitted 6 months or more after the date of the expiration of any previous such waiver for the RHC.

The SA is responsible for reviewing the evidence the RHC provides regarding its efforts to hire a NP, PA or CNM in the previous 90 calendar days and recommending approval or disapproval of the requested waiver to the RO. The SA must complete its review and recommendation within 30 calendar days of receiving the written waiver request from the RHC.

The waiver is deemed to have been granted, unless the waiver request is denied by the RO within

60 calendar days after the date the SA received the RHC's waiver request. In cases where the waiver request is deemed to have been approved, the effective date of the 1-year waiver is the 61st day after the date the request was received by the SA.

See Section 2248 for more details on the waiver process and the expectations for RHCs and SAs

Survey Procedures § 491.8(a)(6)

- Determine what the clinic's total hours of operation are, starting with its weekly schedule. Review hours listed on signs, the RHC's website, if it has one, etc., to determine what the hours of operation are. If the RHC's schedule varies from week to week, review the schedule for a one month period.
- Review staffing schedules for any NPs, Pas, or CNMs on the clinic's staff for the previous two months, as well as their upcoming schedule for the next month.
- Verify that the total scheduled hours for these types of practitioners are at least 50 percent of the total hours the RHC is open.
- Spot check a few clinical records to confirm that the practitioner was actually on-site and seeing patients on several of the days where they were listed as present on the staff schedule.
- Review physician's schedule to assist in verifying that the required medical personnel are on site at all times the RHC is open and operating.

J-0100

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§491.8(b) Physician responsibilities. The physician performs the following:

- (1) . . . provides medical direction for the clinic's . . . health care activities and consultation for, and medical supervision of, the health care staff.
- (3) . . . provides medical orders, and provides medical care services to the patients of the clinic or center.

Interpretative Guidelines § 491.8(b)(1) & (3)

In accordance with § 491.8(b), the MD or DO physician who serves as the RHC's medical director in accordance with § 491.7(a)(1) is responsible for the overall medical direction of the clinic's clinical activities. He or she also provides clinical consultation to and supervises the other physician(s) as well as the non-physician practitioners on the RHC's health care staff. This requirement for "supervision" does not limit the ability of non-physician practitioners to practice in accordance with their State scope of practice. For example, if State law permits an NP to practice independently when providing diagnosis and treatment, including writing orders and prescriptions, the NP would be permitted to do so in the RHC as well. However, the NP, like any other member of the clinic's staff of health care practitioners, would be under the overall medical supervision of the clinic's medical director, who is responsible for the quality of care in the clinic.

In addition to medical direction as described above, the physician must provide assessment, diagnosis, and treatment of patients, and provide medical orders for patients in need of diagnostic tests and/or therapeutic treatments.

If the clinic has more than one physician on its staff, the other physician(s) may also provide medical services, medical orders, and consultation, but only one physician, who must be an MD or DO, can serve as the clinic's medical director and provide overall direction to its clinical activities.

NOTE: To ensure continuity of care, it is permissible to use a locum tenens (i.e., temporary) MD/DO as the medical director of the RHC, providing that same MD/DO is contractually bound to provide services to the clinic for a minimum of six months.

A physician is not required to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no other physician, NP, CNM, PA, clinical social worker or clinical psychologist is present in the RHC. With the development of technology that facilitates telemedicine, a physician has the flexibility to use a variety of ways and timeframes to provide medical direction, consultation, supervision, clinical record review, including being on-site at the facility to provide medical care services to patients. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate based on the needs of the clinic, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician on-site presence that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.

Survey Procedures § 491.8(b)(1) & (3)

- Ask the clinic's medical director how he or she provides overall medical direction and supervision for the clinic.
- Review a sample of pertinent clinic records. Is there evidence in the sample of clinical records reviewed that a physician provided assessment, diagnosis, or treatment services and/or wrote orders for patient testing and/or care?

J-0101

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[§ 491.8(b) Physician responsibilities. The physician performs the following:]

(3) Periodically reviews the clinic's . . . patient records . . .

§ 491.8(c) Physician assistant and nurse practitioner responsibilities.

(1) The physician assistant and the nurse practitioner members of the clinic's staff:

(ii) Participate with a physician in a periodic review of the patients' health records.

Interpretative Guidelines § 491.8(b)(3) & (c)(1)(ii)

A physician must review periodically the RHC's patient clinical records. In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, an RHC physician must review and sign all such records. If there is more than one physician on the RHC's staff, it is permissible for staff physicians other than/in addition to the medical director to review and co-sign the records.

The RHC's NP(s) and/or PA(s) must participate in the physician's review of the clinical records. Participation may be face-to-face or via telecommunications. If there is more than one NP or PA in the clinic, the NP or PA would participate only in the review of records of those patients for which the NP or PA provided care.

Where co-signature is not required, the regulation still requires periodic physician review of the clinical records of patients cared for by non-physician practitioners. If the RHC has more than one physician on its staff, it is permissible for physicians other than/in addition to the medical director to conduct the periodic review of clinical records, so that this task might be divided or shared among the physicians.

If the RHC has more than one physician, its policies and procedures must specify who is authorized (i.e. whether it is the medical director alone, or may include other staff physicians) to review and, if required under State law, co-sign clinical records of patients cared for by a non-physician practitioner.

The regulation does not specify a particular timeframe to satisfy the requirement for "periodic" review of clinical records, but the RHC must specify a maximum interval between record reviews in its policies and procedures. The RHC is expected to take into account the volume and types of services it offers in developing its policy. For example, an RHC that has office hours only one day per week would likely establish a different requirement for record review than an RHC that is open 6 days per week/ 10 hours per day. Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the RHC has electronic clinical records that can be accessed and digitally signed remotely by the physician, this method of review is acceptable. Therefore, RHCs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.

Survey Procedures § 491.8(b)(3) & (c)(1)(ii)

- Ask the clinic's staff what its policy is for the interval at which clinical records will be periodically reviewed. Ask when the last review took place, and request documentation of the review.
- If State law requires co-signature of NP and/or PA orders by a physician, is there evidence in the clinical record of such co-signatures?
- If the RHC has more than one physician, ask whether its policy permits physicians to share the responsibility for the periodic record review.
- Ask how the RHC ensures that all records of patients cared for by non-physician practitioners are periodically reviewed.
- Is there documentation supporting that the required reviews have occurred?

J – 0102

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§ 491.8(c)(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

- (i) Provides services in accordance with the clinic's . . . policies;**
- (ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic . . . ; and**
- (iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.**

Interpretative Guidelines § 491.8(c)(2)

The NP or PA must perform the following functions if they are not being performed by a physician:

- Providing health care services in accordance with the RHC's written policies. However, non-physician practitioners must also operate within their State-permitted scope of practice and may not provide clinic services that require a broader scope of practice;
- Arranging for or referring patients to services which cannot be provided at the RHC; and
- Ensuring that adequate patient health records are maintained. If a patient is referred for additional treatment elsewhere, the NP or PA must ensure that the records are transferred.

Survey Procedures § 491.8(c)(2)

- Ask the RHC's owner, or person in charge of operations for the RHC's policies governing which services may be provided by an NP or PA, whether there are any RHC services that are outside the scope of practice of an NP or PA.
- Interview NPs and/or PAs about the services they provide. If the RHC provides services that are outside their scope of practice, ask what they do if a patient requires such services when no MD or DO is available.
- Verify how new practitioners are made aware of the clinic's patient care policies.
- Ask to review medical records of patients who have been referred to health care services outside of the clinic. Confirm that an MD, DO, NP, or PA arranged for the referral. Is there evidence that appropriate portions of the patient's RHC record were transferred?
- Review patient care records for patients being treated by and NP or PA. Do the NP or PA make entries into the record documenting the care they provide? Were the patient's health records appropriately maintained, and were those records transferred with the referred patient?

J-0120

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.9 Provision of services.

Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance.

J-0121

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.9(a) Basic requirements:

(1) All services offered by the clinic . . . are furnished in accordance with applicable Federal, State, and local laws; and

Interpretative Guidelines § 491.9(a)(1)

The regulation at § 491.4 also requires compliance with applicable Federal, State and local laws. Accordingly, the guidance and survey procedures for that regulation also apply to § 491.9(a)(1).

J-0122

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.9(a) Basic requirements:]

(2) The clinic . . . is primarily engaged in providing outpatient health services and meets all other conditions of the subpart.

(c) Direct services – (1) General. The clinic...staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions

§ 491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Direct services mean services provided by the clinic's staff.

Interpretative Guidelines § 491.9(a)(2) & (c)(1)

An RHC is required to be primarily engaged in providing outpatient or ambulatory health care services. In accordance with §§ 405.2411 - 2416, RHC services include the services of physicians, NPs, PAs, certified nurse midwives, clinical psychologists and clinical social workers, along with the services and supplies that are incident to these practitioners' services. In accordance with § 491.9(c)(1), the services of these practitioners are those commonly furnished in a physician's office or at the entry point into the health care delivery system. These services include taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs and family planning. Further, some RHCs may provide VNS if a request is submitted to the SA and approved by the CMS RO.

RHCs are not prohibited from furnishing other services, for example, ambulatory surgical procedures or diagnostic imaging services. However, they may not be primarily engaged in providing such specialized services. In the context of an RHC, "primarily engaged" is determined by considering the total hours of an RHC's operation, and whether a majority, i.e., more than 50 percent, of those hours involve provision of RHC services.

An example of a clinic schedule that combines RHC with other services would be a clinic that provides RHC services 9 a.m. to 4 p.m. Monday through Friday, and also offers diagnostic imaging services Tuesday and Friday afternoons from 1 p.m. to 4 p.m. The RHC is furnishing 35 hours of standard RHC services and 6 hours of imaging services, for a total of 41 hours of service. In this example, the RHC provides RHC services 85 percent of the time; therefore, it is "primarily engaged" in providing RHC services.

For clinics with a limited schedule, it may be more appropriate to consider the monthly total operating schedule verses the weekly schedule.

Survey Procedures § 491.9(a)(2) & (c)(1)

- Review the clinic's website, and ask the clinic director to describe the types of services the clinic offers. Does it include specialty services that are not RHC services? If yes:
- Review the hours the specialty services are available and the hours RHC services are available, to determine whether the majority of time the RHC provides RHC services.
- Review a sample of patient health records covering at least the two previous months to determine the majority of specific services actually furnished.

J-0123

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§ 491.8(b) Physician responsibilities. The physician performs the following:]

(2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's . . . written policies and the services provided to Federal program patients.

[§ 491.8(c) Physician assistant and nurse practitioner responsibilities.]

(1) The physician assistant and the nurse practitioner members of the clinic's . . . staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic . . . furnishes;

[§ 491.9(b) Patient care policies . . .]

(1) The clinic's ... health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic . . . staff.

(4) These policies are reviewed at least *biennially* by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic . . .

Interpretative Guidelines § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

The clinic must have written policies governing the clinical services provided. At least one RHC physician and one RHC PA or NP must participate in the development of the clinic's written policies and providing advice to the RHC's management on appropriate clinical policies. In addition, there must be at least one physician, NP, or PA who is not on the RHC's staff who participates in the development of the clinical policies. The clinic must identify in writing the names of all individuals involved in developing clinical policies. The clinical practitioners who participate in the policy development provide advice to the RHC's leadership. The RHC's leadership is not required to accept this advice, but if it exercises its authority to reject or modify the patient care policy advice of the practitioners it must be able to ensure that any changes it makes are clinically appropriate and supportable.

The clinic's patient care policies must be reviewed at least *biennially* or more frequently when appropriate, by a group that also contains at least one RHC physician, one RHC NP or PA, and one outside healthcare practitioner.

Survey Procedures § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

- Review meeting minutes or other documentation to verify that the required types of practitioners actually participated at least *biennially* in developing the policies and recommending policies to the RHC's leadership.
- Ask the RHC's leadership if it ever rejects the advice of the practitioners. If yes, how does it ensure that any changes made are clinically appropriate? Does it document the rationale for its rejection of the advice? Is there documentation of the policies recommended by the practitioners as well as of any changes made by the RHC's leadership?

J-0124

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.9(b) Patient care policies.]

(3) The policies include:

(i) A description of the services the clinic . . . furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic . . .

Interpretative Guidelines § 491.9(b)(3)(i) & (ii)

The written RHC patient care policies must include:

Description of Services

The written policies must provide a description of the services the RHC furnishes, whether directly using RHC staff or through an agreement or arrangement. The services furnished by the clinic must be described in sufficient detail to permit understanding of the scope of all services furnished in the RHC, and the scope/type of agreement or arrangement they are furnished through if applicable. An example of services under arrangement might be provision by a contractor of additional laboratory services beyond those required to be performed by RHC staff. Such statements as the following may sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning. Statements such as “complete management of common acute and chronic health problems” standing alone, would not sufficiently describe services.

Guidelines for Medical Management

The clinic’s written guidelines for the medical management of health problems include a description of the scope of medical care that may be furnished by a PA, NP, or CNM, including the extent and nature of required supervision. The guidelines would also include standard protocols for diagnosis and treatment of common conditions or for provision of preventive care. Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self-limiting health problems, and medical emergencies. The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which such topics as the following are discussed: The definition of the condition; its etiology; its clinical features; recommended laboratory studies; differential diagnosis, treatment procedures, complications, consultation/referral required; and follow-up. Guidelines also may be based on guidelines of nationally recognized professional organizations, which are referenced and reproduced, such as the immunization guidelines developed by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. However, the guidelines must include information on actions non-physician practitioners in the RHC are permitted to take, as well as circumstances warranting referral.

Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must:

- Be comprehensive enough to cover most health issues covered in a primary and preventive care setting;
- Describe the actions a NP, PA or CNM may initiate or implement, consistent with State scope of practice requirements; and
- Describe the circumstances that require consultation with the RHC's MD or DO, as well as external referral.

Guidelines may be in electronic or paper format, but should be readily accessible to RHC practitioners, all of whom must be familiar with them.

Survey Procedures § 491.9(b)(3)(i) & (ii)

- Ask the RHC to provide a copy of its description of services. Is it consistent with services advertised on the RHC's website or via other media?
- Ask the RHC's medical director to show one or more medical management guidelines and explain their source/how they were developed, as well as how they are used. Do the examples include the required elements?
- Ask one or more RHC practitioners to demonstrate how they access the RHC's medical management policies. Are they familiar with the guidelines applicable to their practice?

J-0125

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§ 491.9(b) Patient care policies.]

(3) The policies include:

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

Interpretive Guidelines § 491.9(b)(3)(iii)

The RHC's written patient care policies must address storage, handling, and administration of drugs and biologicals within the RHC. The policies must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (USP) (www.usp.org); the American Society of Health-System Pharmacists (<http://www.ashp.org/>); the Institute for Safe Medication Practices (<http://www.ismp.org/default.asp>); the National Coordinating Council for Medication

Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (<http://www.ihl.org/ihl>); and the Infusion Nurses Society (<http://www.insl.org>).

The RHC's policies must address the following:

Storage of drugs and biologicals

Consistent with accepted professional principles, RHC's must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

Proper environmental conditions

Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the RHC is expected to follow the labelled conditions. RHC's must exercise caution in administering any drug or biological that is not labelled to indicate proper storage conditions or that may have been stored under inadequate conditions.

Security

The RHC must have policies and procedures that are consistent with State and Federal law to address how drugs and biologicals are stored and secured, including who is authorized access to the drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are generally considered secure. Areas restricted to authorized personnel only would generally be considered "secure areas."

RHCs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff members are actively providing care to patients or preparing to receive patients, i.e. setting up for injections, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked, in accordance with state and Federal law.

If the RHC uses cart(s) containing drugs or biologicals, whenever the cart is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be within close eyesight of and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and RHC policy is authorized access to the drugs and biologicals in the cart. That individual must

monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

Record keeping for the receipt and disposition of all scheduled drugs.

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five "schedules," ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

The RHC is required to accurately track the receipt and disposition of all scheduled drugs used in the RHC. Components of a record system for scheduled drugs would include:

- Locked storage of scheduled drugs when not in use;
- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs;
- Tracking movement of all scheduled drugs from the point of entry into the RHC to the point of departure either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
- Prompt reconciliation of any discrepancies in count. The RHC is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

Handling drugs and biologicals.

"Handling" includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug's manufacturer.

Compounding

"Handling" also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either facility staff or a contracted pharmacy service.

Generally, RHCs are not settings that use compounded sterile preparations (CSPs) nor are CSPs typically furnished as part of the RHC's services. However, some RHCs may provide additional services beyond RHC services and these might include use of CSPs. If an RHC uses CSPs, it is responsible to ensure that compounding is performed consistent with accepted professional principles.

Generally even if an RHC uses CSPs, it would not be likely to have its own pharmacy that could meet the *standards of practice* for preparation of CSPs; it is more likely that an RHC that uses CSPs would be acquiring them from an external source. The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

- Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA’s publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>;
- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

In a January 2014 letter to purchasers of compounded medications (available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm>), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that, “[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at: <http://www.fda.gov/drugs/guidancecomplianceinformation/pharmacycompounding/ucm378645.htm>

Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.”

Use of Compounding Pharmacies

If an RHC uses compounded medications and obtains them from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the RHC must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- Ensuring that the RHC has access to quality assurance data verifying that the vendor is adhering to *standards of practice for compounding medications*, and can the *RHC* document that it obtains and reviews such data?
- Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?
- Note that these types of compounding pharmacies are also popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board.

Expiration & Beyond Use Dates

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.

A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available.

Basic safe practices for medication administration within the RHC

The RHC’s patient care policies must reflect accepted standards of practice that require the following information be confirmed prior to each administration of medication that takes place in the RHC (such as administration of vaccines or medications via injection):

- Right patient: ensuring the patient's identity. Acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the RHC; or date of birth. Identifiers must be confirmed by patient identification card, patient statement (when possible), or other means outlined in the RHC's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.
- Right medication: the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;
- Right dose: the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);
- Right route: the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc. - is the appropriate one for that particular medication and patient; and
- Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

NOTE: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error.

RHCs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

Survey Procedures § 491.9(b)(3)(iii)

- Are drugs and biologicals stored in a secure manner?
 - Are drugs stored in areas not accessible to unauthorized personnel?
 - When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up?

- Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.
- When applicable, determine if the RHC has a system that tracks movement of all scheduled drugs from the point of entry into the RHC to the point of departure, either through administration to the patient, destruction of the drug, or return to the manufacturer.
 - Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?
- Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the RHC to reconcile and address the discrepancies?
- Interview the person responsible for drug storage as well as other RHC staff to determine their understanding of the RHC's controlled drug policies.
- If the RHC uses CSPs and obtains them from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding?
- Spot-check to identify if expired or unusable medications, including when applicable medications that are past their BUD, are being used for patient care in the RHC.
- Ask what type of personnel administer drugs and biologicals within the RHC, including, if applicable, IVs. Are they practicing within their permitted scope?
- Observe medication administration to verify whether staff members confirm the "5 rights" of medication administration, i.e., the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the RHC's policies and procedures?

J-0135

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.9(a) Basic requirements:]

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, . . .

[§ 491.9(c) Direct services]

(2) **Laboratory.** These requirements apply to RHCs The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides

basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

- (i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);**
- (ii) Hemoglobin or hematocrit;**
- (iii) Blood glucose;**
- (iv) Examination of stool specimens for occult blood;**
- (v) Pregnancy tests; and**
- (vi) Primary culturing for transmittal to a certified laboratory.**

Interpretative Guidelines § 491.9(a)(3) & (c)(2)

Basic laboratory services must be provided in the RHC by RHC staff in order to facilitate the immediate diagnosis and treatment of the patient. To the extent permitted under State and local law, the 6 basic laboratory services listed in § 491(c)(2) are considered the minimum laboratory services the RHC must have available within the clinic, provided by RHC staff. If any of these laboratory services cannot be provided at the RHC due to a State or local law prohibition, that laboratory service is not required for Medicare certification. These laboratory services must be provided in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements at 42 CFR Part 493 operating under a current CLIA certificate appropriate to the level of services performed. However, compliance with CLIA requirements is not assessed by surveyors conducting RHC surveys. Surveyors should, however, ask to see the RHC's CLIA certificate.

RHCs may also provide additional laboratory services, either on-site or through an off-site arrangement, but if it does so, these optional services must also comply with the CLIA requirements. For example, an RHC may have an arrangement with some other provider of clinical laboratory services. However, such arrangements are not permitted to substitute for the requirement to actually provide the 6 basic laboratory services within the RHC, by RHC staff.

Survey Procedures § 491.9(a)(3) & (c)(2)

- Verify that the RHC offers the 6 required basic laboratory services on site. If it does not, is there a State law that prevents the RHC from doing so?
- Verify that all laboratory services are operating under a current, appropriate CLIA certificate, including for additional services provided in the RHC beyond the minimum required 6 basic laboratory services.

(Rev. 194, Issued: 10-25-19, Effective; 10-25-19, Implementation: 10-25-19)

[§ 491.9(c) Direct services]

(3) Emergency. The clinic . . . provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

Interpretative Guidelines § 491.9(c)(3)

The RHC ensures staff is available to appropriately handle medical emergencies as a first response to common life-threatening injuries and acute illnesses at all times the clinic operates. The clinic maintains the types and quantity of drugs and biologicals commonly used by first responders in accordance with accepted standards of practice. The RHC's patient care policies are expected to address which drugs and biologicals it maintains for emergencies and in what quantities. The RHC must maintain a supply of commonly used drugs and biologicals adequate to handle the volume and type of medical emergencies it typically encounters. The following are categories of drugs and biologicals commonly used in life saving procedures:

- Analgesics;
- Local Anesthetics;
- Antibiotics;
- Anticonvulsants; and
- Antidotes, emetics, serums & toxoids.

While each category of drugs and biologicals must be considered, all are not required to be stored. For example, it is appropriate for a RHC to store a small volume of a particular drug/biological, if it generally handles only a small volume/type of a specific emergency. Likewise, it may be acceptable if the clinic did not store a particular drug/biological because it is located in a region of the country where a specific type of emergency is not common (e.g., snake bites). Nonetheless, when determining which drugs and biologicals it has available for purposes of addressing common life-threatening injuries and acute illnesses, the RHC should consider, among other things, the community history, the medical history of its patients and accepted standards of practice. The clinic should have written policies and procedures for determining what drug/biologicals are stored and that address the process for determining which drugs/biologicals to store, including identifying who is responsible for making this determination. The RHC should be able to provide a complete list of the drugs/biologicals that are stored and in what quantities.

Survey Procedures § 491.9(c)(3)

- Review the RHC's written policies and procedures to determine the types and quantities of drugs/biologicals it stores for medical emergency purposes,

- Review all of the drugs/biologicals that are stored and available in the RHC, including in what quantities, to verify the RHC maintains a supply of commonly used drugs and biologicals adequate to handle the volume and type of medical emergencies it typically encounters.
- Ask RHC staff how they determine the quantity and specific types of drugs and biologicals to have on hand. How do they ensure that the specified drugs and biologicals are on hand in the quantities specified per RHC policy and have not expired?
- Any findings as a result of the inquiry, may lead to noncompliance under 42 CFR 491.9(b).

J-0140

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.9(d) Services provided through agreements or arrangements.

(1) The clinic . . . has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

Interpretative Guidelines § 491.9(d)

The clinic has referral agreements with at least one Medicare/Medicaid-participating:

- Hospital or CAH, for inpatient acute care;
- Physician;
- Diagnostic testing facility (which could be a hospital or CAH or a freestanding diagnostic testing facility) for ambulatory diagnostic tests not furnished in the RHC; and
- Clinical laboratory, for laboratory services not furnished in the RHC.

The referral arrangements do not have to be in writing, but if they are not there must be evidence that RHC patients referred for additional services are being accepted and treated by the provider/supplier they are referred to.

Survey Procedures § 491.9(d)

- Determine whether the RHC has referral arrangements with at least one of each of the specified types of providers and suppliers.
- If the referral agreements are not in writing, ask the RHC for evidence that referred patients are being accepted for treatment.

J-0150

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.10 Patient health records

Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance.

J-0151

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.10(a) Records system.

- (1) The clinic . . . maintains a clinical record system in accordance with written policies and procedures.
- (2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized

Interpretative Guidelines § 491.10(a)(1)-(2)

The RHC must maintain a complete, comprehensive and accurate clinical record (also referred to as a medical record) for each RHC patient. The RHC must use the information contained in each clinical record in order to ensure the delivery of appropriate care to each RHC patient.

The RHC must have a designated member of its professional staff (which may be an administrative professional rather than a clinical professional) who is responsible for the RHC's clinical record system. That individual is responsible for developing and implementing, with approval of the RHC's professional staff and leadership, written clinical record policies and procedures.

A RHC that has an electronic health record (EHR) system may be part of a larger EHR system or may participate in a systematic exchange of patient health care information to promote good patient care. In either instance, only the appropriate RHC staff may have access to the medical records of RHC patients. The RHC's written clinical records policies and procedures reflect that it is part of a larger system or exchange, when applicable. Further, even when the RHC participates in a larger EHR system, the clinical records for all RHC visits must still meet the requirements of the RHC Patient Health Records Condition and must be readily retrievable and distinguishable from other information in the shared EHR system.

The RHC must also comply with the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules at 45 CFR Parts 160 and 164 when sharing clinical record information that is Protected Health Information. However, CMS does not interpret or assess compliance with HIPAA requirements, and thus surveyors also are not authorized to assess HIPAA compliance. If surveyors suspect a serious breach of HIPAA, they should refer their concerns to the regional U.S. Department of Health & Human Services Office of Civil Rights.

Complete and accurate

All clinical records entries must be legible, i.e., able to be read clearly and unambiguously. Any entries or information contained in the clinical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.

The clinical record must also be complete, i.e., it must contain for each patient at least the information required at § 491.10(a)(3). Implicit in the requirement for the record to be complete is an expectation that all entries of required information are made into the clinical record promptly, so that it is available to subsequent caregivers. The clinical record must be complete.

The RHC must ensure that all clinical records are accurately written. All clinical records must contain the correct information for the correct patient. The identity of the patient must be clear through use of identifiers such as name, date of birth, etc. The RHC may have a system in place that assigns a unique patient identifier to each patient, such as a medical record number or financial identification number. If the RHC has such a system in place, its clinical records policies and procedures must address the manner in which the unique identifiers are generated and assigned to each individual patient. The RHC must also take steps to ensure the accurate identity of the patients if using unique identifiers.

Entries in the clinical record may be made only by individuals authorized by the RHC in accordance with its written policies and procedures to do so, and must be dated, timed, and authenticated by the individual making the entry. When authenticating the entry, the author indicates by his/her signature/authentication that the entry is accurate. Entries

made on behalf of a practitioner by authorized individuals must also be promptly dated, timed, and authenticated by the practitioner. A clinic policy stating that a practitioner must disapprove an entry within a specific time period or the entry is by “default” authenticated is **not** acceptable; the practitioner must affirmatively authenticate each entry.

The RHC must have in place a method to identify the author of each entry and to ensure that entries are not made by any individual using another individual’s identity. For example, if the RHC uses an EHR system that requires individuals to use passwords or card keys to access the system, individuals may not share their passwords or card keys with other individuals. Likewise, if the RHC uses a paper clinical record system and authorizes the use of rubber stamps for signatures, the individual whose signature the stamp represents must **not** allow any other individual to use it.

Readily accessible

The clinical record must be readily accessible to RHC staff. The RHC must have a clinical record system that allows clinical staff timely access when needed to all open records, i.e., records of all RHC patients who, per clinical record policy, are considered to still be active RHC patients. The clinical records policies and procedures must also address how long closed clinical records will be readily accessible to staff (This is distinguishable from the 6 year retention of closed records requirement at §491.10(c)).

The RHC’s clinical record system must be systematically organized to facilitate completion, storage, and retrieval of records in a manner that supports timely provision of evaluation or treatment services to RHC patients.

Survey Procedures §491.10(a)(1)-(2)

- Verify that the RHC has written policies and procedures governing its clinical record system.
 - Do not review the policies and procedures unless observations, interviews or record reviews indicate noncompliance with the requirements of the Clinical Records Condition. At that time, ask to review the pertinent policies and procedures to determine whether the noncompliance is based on deficient policies or based upon failure to implement compliance policies.
- Verify a professional staff member has been designated responsible for the RHC’s clinical record system.
- Ask the responsible individual whether there have been changes in the system, e.g., adoption of a partial or full EHR system, and, if so, for evidence that the RHC’s policies and procedures were updated to reflect the clinical record system currently in use.

- If the RHC has an EHR system, immediately after the entrance conference interview, ask the person who is responsible for the RHC's clinical record system to give an overview of the EHR system, including:
 - Whether there is one system that is fully integrated throughout the RHC or a hybrid EHR-paper record system. In the case of a hybrid system, have the RHC identify which parts of the RHC use which systems. Ask how the RHC ensures that the clinical record is complete, accurate, and accessible in this hybrid environment;
 - What the arrangements are in the event of an EHR system failure, to ensure that complete and accurate medical records are accessible;
 - Observe how staff members use the EHR system to determine whether they are able to access complete clinical record information when needed. When applicable, observe whether or not staff members make entries promptly?
 - If the RHC shares an EHR system with other providers, is the RHC able to demonstrate that the RHC's clinical records are readily identifiable, distinguishable from other information in the shared system and accessible by appropriate RHC staff members only?
 - If the RHC uses a partial or whole paper clinical record system, are records legible?
- When reviewing sampled clinical records is there evidence that any of the records are inaccurate or incomplete?
 - Is each entry dated, timed, and authenticated?
 - If RHC policy permits authorized individuals to make entries on behalf of a practitioner, has the practitioner promptly authenticated the entry?
 - Is each clinical record systematically organized?
- Are the medical records organized in a systematic manner allowing easy retrieval?

J-0152

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.10(a) Records system.]

(3) For each patient receiving health care services, the clinic . . . maintains a record that includes, as applicable:

- (i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;**
- (ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;**
- (iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;**
- (iv) Signatures of the physician or other health care professional.**

Interpretative Guidelines §491.10(a)(3)(i) - (iv)

The clinical record for each RHC patient must contain at least the following information:

Identification and Social Data

The clinical record must contain information that allows the identity of the patient to be clear through the use of patient identifiers such as name, date of birth, etc.

“Social data” may include the patient’s address, work information, insurance information, names of family members, designated representative (if any), etc.

Informed Consent

The RHC must have written patient care policies that address the circumstances when the patient’s informed consent to diagnosis or treatment is required, and under what emergency circumstances the informed consent requirement may be waived.

The clinical record must include a record of the patient’s (or that of the patient’s representative, determined in accordance with State law) informed consent in all cases where the RHC’s policies require informed consent. If there is applicable Federal or State law requiring informed consent, the RHC must comply with those requirements, but compliance is not assessed as part of the survey of the RHC’s compliance with the CfCs.

The clinical record must provide evidence the informed consent was properly executed. A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the RHC’s informed consent policies, all clinical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with RHC’s policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- Name of the specific procedure(s), or other type of diagnosis or treatment for which consent is being given;

- Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's representative (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity). RHCs are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits, and alternatives will be discussed with the patient.
- Signature of the patient or the patient's representative; and
- Date and time the informed consent is signed by the patient or the patient's legal representative. If the RHC uses an EHR system, signature may be electronic. However, there must be documentation of how the patient's or representative's electronic signature is verified within the EHR system and may not be altered. Likewise, there must be documentation that makes clear what the patient or representative consented to and how alteration is prevented.

If there is applicable State law governing the content of the informed consent form, then the RHC's form must comply with those requirements.

Pertinent Medical History

The purpose of a medical history is to determine whether there is anything in the patient's overall condition that would affect the patient's diagnosis or planned course of treatment, such as a prior occurrence of similar symptoms, a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce adverse health risks to the patient.

Only qualified personnel as determined by RHC policy may enter the medical history into the clinical record, but in all cases, the medical history must be reviewed and authenticated promptly by a practitioner. The RHC must have written policies and procedures specifying when a new or updated medical history is required.

Assessment of the Health Status and Health Care Needs of the Patient

The clinical record must include assessment by a practitioner of the current health status and health care needs of the patient at the time of each RHC visit.

Brief Summary of the Episode, Disposition, and Instructions to the Patient

There must be a brief summary of the reason for the RHC visit and the patient's disposition, including any follow-up instructions provided to the patient. Only qualified personnel as determined by RHC policy may enter the summary into the clinical record, but in all cases the summary must be authenticated promptly by a RHC practitioner.

Reports of Physical Examinations

Physical examinations performed on the patient are typically conducted at the time the pertinent medical history is being collected, but may also be conducted at other times. The physical examination must be completed by a practitioner and documented and authenticated in the clinical record by a practitioner in accordance with State law and RHC policy.

Diagnostic and Laboratory Test Results

All results of diagnostic and laboratory tests that are performed by the RHC directly or under arrangement must be included in the patient's clinical record. Any interpretations of tests by a practitioner must be authenticated by the practitioner.

Consultative Findings

All findings of a practitioner who provides consultation at the request of a RHC practitioner on a RHC patient, and who reports those findings to the RHC practitioner, must be included in the patient's clinical record.

Other Required Content

The clinical record must also contain:

- Practitioner's orders, dated, timed, and signed, for all tests, medications, treatments, and any other matters requiring an order from a practitioner;
- Nursing notes, properly authenticated, for all patients reflecting all nursing care provided;
- Documentation of all treatments furnished (including any complications that occurred) by the practitioner furnishing the care;
- Documentation of all medications administered (including adverse drug reactions) by the person administering the medication;
- Documentation of the patient's response to all treatments furnished; and
- Evidence of other pertinent information required to monitor the patient's progress, such as vital signs.

Survey Procedures § 491.10(a)(3)(i) – (iv)

- Determine whether there is a medical history for each RHC patient whose clinical record is reviewed. Is there evidence that a practitioner reviewed the medical history?
- Ask the RHC what its policy is for updating a patient's medical history; ask for documentation of the policy.
- When applicable, determine if clinical records in the sample being reviewed include an updated medical history.
- Determine whether the RHC has adopted policies and procedures addressing when an informed consent is required.
- Determine whether there is an informed consent when required in the medical record, and that it contains the minimum required elements as well as any additional elements required under RHC policy.
- In records reviewed, is there evidence of:
 - The practitioner's assessment of the patient's health status and health care needs?
 - A documented summary of the visit, including the required regulatory information?
 - Physical examination findings, diagnostic and laboratory test results, and consultative findings.
 - Are findings and test reports appropriately authenticated by a practitioner?

J-0153

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§ 491.10(b) Protection of record information.

- (1) The clinic . . . maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.
- (2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.
- (3) The patient's written consent is required for release of information not authorized to be released without such consent.

Interpretative Guidelines § 491.10(b)

The RHC must have sufficient safeguards to ensure that access to all information regarding patients is limited to authorized individuals only. Whether in paper or electronic format, clinical records must be protected from loss or unintended destruction, and must be protected from access by unauthorized individuals or unauthorized used by authorized individuals. However, the nature of the safeguards the RHC uses will vary depending on the medium in which records are created and stored. For example, closed paper records might be locked in a secure area that is protected from environmental hazards, such as fire, floods, humidity, etc., while open paper records might be kept in an area where access is limited to authorized personnel. On the other hand, safeguards for EHR systems might be focused on back-up electrical power, arrangements for backing up information at a remote server, and limiting access through use of passwords, card readers, etc.

The RHC's clinical record policies and procedures must address who may use clinical records, how they may use them, who may "remove" clinical records (i.e., physically removing paper records or films, or deleting records from an EHR system), and under which conditions information in a clinical record may be released, and to whom.

Prior to releasing information from their clinical record, the RHC must obtain the written consent of the patient who is the subject of the record (or his/her representative), unless the release is required by law. Note that uses and disclosures of protected health information (PHI) which are, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR parts 160 and 164, Subparts A and E), made without the patient's prior authorization are considered to also be permissible under the RHC CfCs and do not require the written authorization specified in § 491.10(b)(3). Note that CMS and State surveyors conducting surveys on behalf of CMS are not authorized to assess compliance with the HIPAA Privacy Rule, which is interpreted and enforced by the U.S. Department of Health and Human Services Office of Civil Rights (OCR). If surveyors and their managers have concerns about disclosures that the RHC makes without the written consent of the patient (or the patient's representative), they should refer such concerns to the Regional OCR office.

Survey Procedures §491.10(b)

- Verify that only authorized persons are permitted access to clinical records.
- Observe the RHC's security practices for patient records. Are paper clinical records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, or on counters where an unauthorized person could gain access to patient records?
- Verify that precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

- Verify that the RHC has policies and procedures governing disclosure of clinical record information, including when the patient's written consent is required.

J-0154

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§ 491.10(c) Retention of records.

The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

Interpretative Guidelines §491.10(c)

Clinical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The RHC must be able to promptly retrieve the complete medical record of every individual evaluated or treated at the RHC 6 years after the latest entry made into the patient's record. Therefore, clinical records must be maintained within the RHC.

Although RHCs are expected to comply with other Federal or State law requirements calling for longer retention periods, compliance with these other requirements is not assessed as part of the Federal RHC survey.

Survey Procedures §491.10(c)

Determine that records are retained for at least 6 years from the date of the last entry.

J-0160

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.11 Program Evaluation

Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance.

J-0161

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§491.11(a) The clinic . . . carries out, or arranges for, a *biennial* evaluation of its total program.

(b) The evaluation includes review of:

- (1) The utilization of clinic . . . services, including at least the number of patients served and the volume of services;
 - (2) A representative sample of both active and closed clinical records; and
 - (3) The clinic's . . . health care policies.
- (c) The purpose of the review is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

Interpretative Guidelines §491.11(a) - (c)

The clinic's program evaluation must be reviewed at least biennially. This evaluation may be done by RHC staff or through arrangement with other appropriate professionals. The RHC must have documentation of who conducts the review or portions of the review, and what their qualifications are to do so.

The evaluation must include, at a minimum, the number of patients served and the volume of services provided. The evaluation should be able to determine whether the RHC provides appropriate types and volume of services based upon the needs of its patient population. It should also be able to evaluate whether RHC patient policies were followed and whether or not changes to the policies or to procedures are warranted.

A RHC that has been certified for less than one year may not have done a program evaluation. However, the RHC must have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered within the evaluation.

The evaluation must also include a review of a representative sample of both active and closed clinical records of RHC patients. The sample must also include at least 5 percent of the RHC's current patients or 50 records, whichever is less. The purpose of the review is to determine whether utilization of the RHC's services was appropriate, i.e., whether practitioners adhere to accepted standards of practice and adhere to the RHC's guidelines for medical management when diagnosing or treating patients. The review also must evaluate whether all personnel providing direct patient care adhere to the RHC's patient care policies. The evaluation of practitioners must be conducted by an MD or DO; if there is only one MD or DO practicing in the RHC, it is expected that the RHC will arrange for an outside MD/DO to review the selected sample of records of RHC patients cared for by the RHC's MD/DO. The evaluation of whether the RHC's patient care policies were followed may be conducted by an MD/DO, a non-physician practitioner, an RN, or other personnel who meet the RHC's qualifications criteria.

The evaluation findings must be documented in a summary report, and must include recommendations, if any, for corrective actions to address problems identified in the evaluation. If a RHC has developed a QAPI program and that program meets/exceeds the regulatory requirements for a Program Evaluation, the QAPI program would be acceptable.

Survey Procedures § 491.11 (a) - (c)

- Is there evidence that the evaluation *is completed at least biennially and* includes review of the number of patients served and the volume of services provided?
- Is there evidence of a review of a representative sample of RHC records?

- Does the sample include the required minimum number of records?
- Who conducts which portions of the review? Are they qualified to do so?
- Is there evidence of findings and recommendations from the review, and do the findings address each required component?

J-0162

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.11(d) The clinic . . . staff considers the findings of the evaluation and takes corrective action if necessary.

Interpretative Guidelines § 491.11(d)

The RHC's leadership must consider the evaluation findings and recommendations for change, if any. It must take corrective actions as necessary, such as changes in policies or, with respect to clinical personnel, provision of additional training, changes in level of supervision, or even limiting or terminating clinical privileges. The RHC must document where and when the evaluation findings and recommendations were considered, and by whom they were considered. It must also document what corrective actions, if any, were taken and by whom they were recommended. If the RHC leadership does not take corrective actions recommended as part of the evaluation, or if it takes corrective actions different from those recommended, it must document the rationale for its decision.

Survey Procedures § 491.11(d)

- Does the RHC have documentation of leadership review of the evaluation findings each year?
- Is there evidence of the RHC taking corrective actions?
- If the RHC did not take recommended corrective actions or took corrective actions different from those recommended, did it document an appropriate rationale supporting its decision?

Transmittals Issued for this Appendix

3. The Framework

As we described in the CY 2022 PFS proposed rule (86 FR 39247), the framework is a determination process to identify when section 505(b)(2) drug products without an FDA TE rating to an existing drug product payable under Part B correspond to an existing multiple source drug code for the purpose of payment under Medicare Part B. The framework would provide additional detail about the decision-making process and increase transparency about potential determinations resulting from the framework.

The first portion of the framework would compare certain qualities of the section 505(b)(2) drug product with drug products already assigned to an existing multiple source drug code.⁸⁹ This includes comparison of the: (1) Active ingredient(s); (2) dosage form (if part of the drug product name); (3) salt form; and (4) other ingredients in the drug product formulation. The drug product assessment could result in a match or non-match designation. Section 505(b)(2) drug products receiving a match designation in the first portion of the framework would continue to a verification step. This step would compare the pharmacokinetic and clinical studies of the section 505(b)(2) drug product's FDA-approved labeling with those of the drug products already assigned to an existing multiple source code. Finally, a determination would be made as to whether the section 505(b)(2) drug product could be assigned to the existing multiple source code.

For full details on the framework, please see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices>.

We solicited comment on the following:

- The framework and how it aligns with the statutory definitions of single source and multiple source drugs in section 1847A(c)(6)(C) and (D) of the Act, respectively;
- How the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code; and
- The potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders.

We received public comments on the framework, a determination process to

identify when section 505(b)(2) drug products without an FDA TE rating to an existing drug product payable under Part B correspond to an existing multiple source drug code for the purpose of payment under Medicare Part B. The following is a summary of the comments we received and our response.

Comment: Overall, we received 27 comments on the framework approach to assigning certain section 505(b)(2) drug products to existing multiple source codes. A majority of commenters were pharmaceutical manufacturers; other commenters included MedPAC, and professional associations representing stakeholder interests.

We received 14 comments on the framework and how it aligns with the statutory definitions of single source and multiple source drugs. Several commenters noted that CMS lacks the statutory basis for the framework. The commenters stated that the framework does not align with the statutory definition for multiple source drug.

We received six comments on how the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code. Some commenters stated that framework does detect meaningful differences between drug products. However, some commenters stated that the framework is not robust enough and does not consider all of the important elements that would make two drug products meaningfully different. Other commenters suggested modifications to the framework.

We received comments on the potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders. Several commenters expressed concern about potential impacts of the framework on manufacturers' use of the section 505(b)(2) pathway. Commenters stated that implementation of the framework approach would slow innovation by discouraging or disincentivizing manufacturers from using the section 505(b)(2) pathway for drug approval. The commenters also stated that payment for section 505(b)(2) drug products as multiple source drugs could result in inadequate reimbursement, and subsequently, may limit access to patients in the physician office setting.

Lastly, we received comments in support of the framework and the assignment of certain section 505(b)(2) drug products to existing multiple source codes. One commenter agreed that drugs approved under the section 505(b)(2) pathway should be considered for definition as a multiple source drug.

The commenter stated that defining some section 505(b)(2) drug products as multiple source drugs, and potentially assigning lower payment limit, would generate cost savings. MedPAC reiterated their 2021 PFS comment, which supported CMS codifying its longstanding process for assigning certain section 505(b)(2) drug products into multiple source billing and payment codes. A third commenter expressed concern regarding the price of legacy drugs approved through the section 505(b)(2) pathway.

Response: We thank all the commenters for providing feedback on this comment solicitation regarding the framework and how it aligns with the statutory definitions of single source and multiple source drugs; how the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code; and potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders. We will take these comments into consideration for future rulemaking.

F. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA) amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. We have taken steps to implement this program over several years, and codified the AUC program in our regulations at 42 CFR 414.94. In CY 2020, we began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information, which has been extended through CY 2021.

The CY 2016 PFS final rule with comment period (80 FR 70886) addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In the CY 2016 PFS final rule with comment period, we established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS website at the end of June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act.

The CY 2017 PFS final rule (81 FR 80170) addressed the second component

⁸⁹ These assignments are published as part of the ASP NDC–HCPCS Crosswalk Files available at <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files>.

of this program, specification of qualified clinical decision support mechanisms (CDSMs). In the CY 2017 PFS final rule, we defined CDSM, identified the requirements CDSMs must meet for qualification, including preliminary qualification for mechanisms documenting how and when each requirement is reasonably expected to be met, and established a process by which CDSMs may become qualified. We also defined applicable payment systems under this program, specified the first list of priority clinical areas, and identified exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. The first list of qualified CDSMs was posted on the CMS website in July 2017.

The CY 2018 PFS final rule (82 FR 53190) addressed the third component of this program, the consultation and reporting requirements. In the CY 2018 PFS final rule, we established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic imaging services. Specifically, for services ordered on and after January 1, 2020, we established that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the Medicare claim. We further specified that the AUC program will begin on January 1, 2020 with a year-long educational and operations testing period during which time AUC consultation information is expected to be reported on claims, but claims would not be denied for failure to include proper AUC consultation information. We also established a voluntary period from July 2018 through the end of 2019 that ordering professionals who are ready to participate in the AUC program may consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals; and furnishing professionals who are ready to do so may report AUC consultation information on the claim at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10481.pdf>.

Additionally, to incentivize early use of qualified CDSMs to consult AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule (hereinafter “CY 2018 Quality Payment Program final rule”), a high-weight

improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

In the CY 2019 PFS final rule (83 FR 59452), we made further additions and clarifications to the AUC program requirements. We added independent diagnostic testing facility (IDTF) to the definition of applicable settings under § 414.94(b). We also clarified that the furnishing professionals (including provider or supplier entities furnishing advanced diagnostic imaging services in an applicable setting, paid for under an applicable payment system) are required to report AUC consultation information on the claims as specified under § 414.94(k). We established significant hardship exception criteria and process under § 414.94(i)(3) to be specific to the AUC program and independent of other Medicare programs. We specified under § 414.94(j)(2) that when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC consultation with a qualified CDSM. Finally, we announced our intention to use G-codes and modifiers to report AUC consultation information on the Medicare claims. In 2020, in response to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID-19) (PHE for COVID-19), the educational and operations testing period was extended through CY 2021.

1. Background

AUC present information in a manner that links a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation. For purposes of this program, AUC is a set or library of individual AUC. Each individual criterion is an evidence-based guideline for a particular clinical scenario based on a patient presenting symptoms or condition.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information, but may be more effective when they are integrated into EHRs. Ideally, practitioners would interact directly with the CDSM through their

primary user interface, thus minimizing interruption to the clinical workflow.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, “Recognizing Appropriate Use Criteria for Certain Imaging Services,” which directed the Secretary to establish a program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional’s consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). We did not identify mechanisms for consultation by April 1, 2016. Therefore, we did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term “provider-led entity” and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by us, the AUC that are developed, modified or endorsed by the qualified PLE are

considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

In the same rule, we established a timeline and process under § 414.94(c)(2) for PLEs to apply to become qualified. Qualified PLEs are listed at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html> (OMB Control Number 0938-1288).

b. Mechanism for AUC Consultation

In the CY 2017 PFS final rule, we addressed the second major component of the Medicare AUC program—the specification of qualified CDSMs for use by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term CDSM and finalizing functionality requirements of mechanisms, upon which qualification is based, as provided in section 1834(q)(3)(B) of the Act and in the CY 2017 PFS final rule. We defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or a mechanism established by the Secretary.

In the CY 2017 PFS final rule, we established a timeline and process in § 414.94(g)(2) for CDSM developers to apply to have their CDSMs qualified. Qualified CDSMs are listed at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html> (OMB Control Number 0938-1315).

c. AUC Consultation and Reporting

In the CY 2018 PFS final rule, we addressed the third major component of the Medicare AUC program—consultation with applicable AUC by the ordering professional and reporting of such consultations under section 1834(q)(4) of the Act. We established a January 1, 2020 effective date for the AUC consultation and reporting requirements for this program. We also established a voluntary period during which early adopters could begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period, there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On January 1, 2020, the program began with an educational and operations testing period and during this time, we have continued to pay claims whether or not they correctly include AUC consultation information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020; and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020.

Consistent with section 1834(q)(4)(B) of the Act, we also established that the following information must be reported on Medicare claims for advanced diagnostic imaging services as specified in section 1834(q)(1)(C) of the Act and defined in § 414.94(b), furnished in an applicable setting as defined in section 1834(q)(1)(D) of the Act, paid for under an applicable payment system as defined in section 1834(q)(4)(D) of the Act, and ordered on or after January 1, 2020: (1) The qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional).

Section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements in the case of: A service ordered for an individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering

professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship. In the CY 2017 PFS final rule, we adopted a regulation at § 414.94(h)(1)(i) to specify the circumstances under which AUC consultation and reporting requirements are not applicable and in the CY 2019 PFS final rule, we updated the significant hardship exception criteria to be specific to the AUC program and independent of other programs. An ordering professional experiencing any of the following when ordering an advanced diagnostic imaging service is not required to consult AUC using a qualified CDSM, and the claim for the applicable imaging service is not required to include AUC consultation information. Significant hardship exceptions under § 414.94(i)(3) include: Insufficient internet access; EHR or CDSM vendor issues; or extreme and uncontrollable circumstances.

We remind readers that, consistent with section 1834(q)(4)(A) of the Act, ordering professionals must consult AUC for every applicable imaging service furnished in an applicable setting and paid under an applicable payment system unless a statutory exception applies.

Section 1834(q)(4)(D) of the Act specifies the applicable payment systems for which AUC consultation and reporting requirements apply. In the CY 2017 PFS final rule, we defined applicable payment system to reflect the statutory requirements in § 414.94(b) as: (1) The PFS established under section 1848(b) of the Act; (2) the PPS for HOPD services under section 1833(t) of the Act; and (3) the ASC payment system under section 1833(i) of the Act.

Section 1834(q)(1)(D) of the Act specifies the applicable settings in which AUC consultation and reporting requirements apply: A physician's office, a HOPD (including an emergency department), an ASC, and any other "provider-led outpatient setting determined appropriate by the Secretary." In the CY 2017 PFS final rule, we added this definition to § 414.94(b). As noted above, we expanded that definition to add an IDTF in the CY 2019 PFS final rule.

d. Identification of Outliers

The fourth component of the Medicare AUC program is specified in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement that applies for outlier professionals beginning

January 1, 2020, as specified under section 1834(q)(6) of the Act. Because we established a start date of January 1, 2020 for AUC consultation and reporting requirements, we did not identify any outlier ordering professionals by that date. As such, implementation of the prior authorization component is delayed. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

We will use future rulemaking to establish the methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services.

4. Continuing Implementation

a. Clarification of AUC Program Scope

i. Modified Orders

Updates or modifications to orders for advanced diagnostic imaging services may be warranted in certain situations once the beneficiary is under the care of the furnishing professional. Unless they are also serving as the ordering professional, furnishing professionals may not consult AUC on behalf of or in place of the ordering professional. The Medicare Benefit Policy Manual (BPM) (Pub. L. 100–02) addresses situations where the furnishing professional performs imaging services that differ from ordered services in chapter 15, sections 80.6.1–4 (hereafter in this section, “the BPM”). The BPM on modified orders state that when an interpreting physician determines that a different or additional imaging service not included on the order should be performed, the interpreting physician or testing facility generally may not perform the test until a new order from the treating physician/practitioner has been received. If the treating physician/practitioner cannot be reached to change or obtain a new order, the interpreting physician or testing facility may furnish the additional imaging service under the following circumstances, as documented in the patient’s medical

record: The treating physician/practitioner could not be reached, the ordered test is performed and an additional diagnostic test is medically necessary because of the abnormal result of that test, delaying performance of the additional test would have an adverse effect on the patient’s care, the result of the additional test is communicated to and used by the treating physician/practitioner in the patient’s treatment, and the interpreting physician/practitioner documents in the report the reasons for the additional testing.

When the furnishing professional performs additional imaging services not reflected on the order under these circumstances, we do not believe it would be appropriate to consider them to be acting as an ordering professional such that an AUC consultation would be needed. Instead, we believe the furnishing professional in these situations is the interpreting physician/practitioner who is exercising their professional judgment to provide the ordering professional with additional diagnostic test results for use in managing the patient’s care. Additionally, they are doing so only because, after performing the ordered test and determining that additional testing is expedient given the results of that test, the ordering professional cannot be reached to request a modified or additional order. Given the conditions under which these additional imaging services are performed, we proposed that when the furnishing professional for an advanced diagnostic imaging service performs one or more additional services under the circumstances described in chapter 15, section 80.6.2–4 of the BPM, neither the ordering professional nor the furnishing professional are required to consult AUC for the additional service(s). In these situations, the AUC consultation information from the original order is to be reported on the claim line for the additional service(s). Where the furnishing professional modifies the order for an advanced diagnostic imaging service without obtaining a new order from the ordering professional, the AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred. Because the BPM states that the interpreting physician or testing facility generally may not perform a modified or new test until a new order from the treating physician/practitioner has been received, we expect situations where

AUC consultations do not occur for new or modified orders to be infrequent.

We received public comments on the proposal and discussions related to modified orders above. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that CMS does not provide enough data to substantiate that modified orders are infrequent.

Response: We make this statement at the end of the discussion above and after referring to the existing language in the BPM (Chapter 15, sections 80.6.2–4). The BPM states that when an interpreting physician determines that a different or additional imaging service not included on the order should be performed, the interpreting physician or testing facility generally may not perform the test until a new order from the treating physician/practitioner has been received and, if the treating physician/practitioner cannot be reached to change or obtain a new order, only then may the interpreting physician or testing facility furnish the additional imaging service under certain circumstances. Because the expectation is that, except under narrow circumstances, a new or additional order to be placed by the ordering professional, we expect situations where the ordering professional is completely uninvolved, and thus, where we proposed that another AUC consultation would not be performed, to be infrequent. This is not based on information generated from claims or other data as, to the best of our knowledge, claims for modified orders (additional or replacement) do not include unique, identifying information. If orders are in fact being modified frequently, it would suggest to us that practitioners may not be familiar with the provisions of the BPM regarding modified orders.

Comment: Two commenters stated that the proposal conflicts with a response to public comments in the CY 2018 PFS final rule addressing order modifications. These commenters stated that in the CY 2018 PFS final rule, CMS provided guidance that when furnishing professionals must update or modify the order, the AUC consultation information provided by the ordering professional with the original order should be reflected on the claim. These commenters further stated that EHRs implement functionality that automatically applies AUC information from an original order to the modified order without any verification that the requirements for order modification were met. These commenters requested that CMS allow providers to append

modifier MH (indicating that the imaging service was not subject to the AUC program requirements) when the furnishing professional determines a new or modified order should be performed without first requesting the new or modified order to be submitted by the original ordering professional.

Response: We disagree that the above proposal conflicts with the guidance included in the CY 2018 PFS final rule, but rather believe it provides further clarification. These commenters did not reference the CMS response in its entirety which stated that we do not believe it was the intent of section 218(b) of the PAMA to reverse the rules specified in Chapter 15, sections 80.6.2–4 of the Medicare BPM, and we expect furnishing professionals and facilities to continue to adhere to them. After this statement, we then addressed instances when the furnishing professional must update or modify the order and stated that for these situations, the AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred. While the language cited by commenters, when taken out of context of the entire response, appears to instruct practitioners to append the original AUC consultation information to the claim without consideration of ordering professionals submitting an updated order, such interpretation is inconsistent with the whole response which states that we expect furnishing professionals to maintain compliance with the provisions of Chapter 15, sections 80.6.2–4 of the Medicare BPM. As such, the proposals in this year's proposed rule are consistent with prior guidance in rulemaking and existing guidance in the BPM. Additionally, we disagree with the commenter's suggestion that it would be appropriate to append a modifier to claims for such services, indicating that they are not subject to the AUC program requirements. We maintain that when the furnishing professional is unable to reach the ordering professional to obtain a new order and proceeds with additional or different imaging as described in the BPM, the AUC consultation information for the original order is to be appended to the claim for the service(s) ultimately furnished.

Comment: One commenter stated that the proposals for modified orders are confusing and CMS should develop other solutions for how AUC data should be reported on claims for revised/additional advanced diagnostic imaging orders. This commenter further

stated that the proposals appear to require furnishing professionals to report erroneous information about the consultation on the claim which could potentially negatively impact the ordering professional when the program moves into the outlier identification and prior authorization component. This commenter requested that CMS clarify how AUC data should be reported on claims for revised/additional imaging orders and how CMS might mitigate negative downstream effects on ordering professionals whose CDSM data were erroneously reported on claims to accommodate this scenario. Another commenter also requested clarification around the applicability and documentation for modified orders.

Response: While we recognize that the claims processing solutions to fully implement the AUC program are imperfect, particularly since our claims processing systems do not have the capability to fully automate claims processing for advanced diagnostic imaging services subject to the AUC program, we believe the proposal specific to modified orders is clear, appropriate and does not in fact require the reporting of erroneous information on the Medicare claim.

First, the proposal is that, in the event a different or additional service is furnished than was originally ordered under the circumstances described in the BPM, the furnishing professional would report on the claim for the imaging service(s) ultimately furnished the AUC information communicated with the original order by the ordering professional. In these situations, no other AUC consultations take place since, under our proposal, the furnishing professional is not originally and does not become the ordering professional. As such, the only AUC consultation information pertinent to the specific patient in question and for the specific clinical scenario in question was obtained when the ordering professional consulted AUC for the original order, and thus this is the only AUC consultation information that could be appended to the claim. In instances where the furnishing professional determines additional or replacement imaging services should be performed and he or she is able to reach the ordering professional for a new order, then the ordering professional will consult AUC for the new order(s) and provide that information with the new order(s) for inclusion on the claim.

Second, these services, when furnished in an applicable setting and paid under an applicable payment system, are not excepted from the AUC program, so appending a modifier to

indicate that they are, would be erroneous.

Third, we disagree with the suggestion that this approach would result in negative downstream effects for ordering professionals specific to outlier identification and prior authorization as inclusion of the original consultation information on the claim would meet the requirements for the claim to process and communicate the original consultation information to indicate the level of adherence of the order placed by the ordering professional with AUC. This suggestion raises the question whether the modified order parameters set forth in the Medicare BPM are consistently followed. CMS does not have the authority to establish an exception to the reporting requirements. CMS may consider in subsequent rulemaking whether an additional modifier should be appended to all modified orders (additional and/or revised) for which new orders are not submitted by the original ordering professional to ensure that furnishing professionals are not furnishing advanced diagnostic imaging services unilaterally and without the acknowledgement of the ordering professional. An additional modifier to identify these situations could be useful to mitigate any unintended consequences during the outlier identification and prior authorization component. We note that the AUC program is designed to improve ordering patterns of ordering professionals by further educating them on appropriate use of advanced diagnostic imaging services and this may not be achieved if orders are frequently modified without the involvement of the ordering professional.

Comment: Some commenters expressed general support for the proposal. One commenter expressed agreement with the proposal, in the conditions outlined in the proposed rule, that the ordering professional would not be required to consult AUC for imaging studies that need to be modified once under the care of the furnishing professional. Another commenter specifically expressed support for the proposal to except modified orders from the AUC consultation requirement when a different test is clinically appropriate, additional testing may be needed, and the ordering professional is not available to provide a new order. One commenter stated that furnishing professionals should be able to modify the order without obtaining a new order from the ordering professional and use the original AUC on the claim for

modified orders when a radiologist deems it necessary to change the original exam based on best clinical judgement for decisions regarding contrast/non-contrast or scans on contiguous body parts.

Response: We appreciate the comments and remind readers of the specifications in the BPM discussed above.

After consideration of public comments we are finalizing our proposal without change so that furnishing professionals that modify an order for advanced diagnostic imaging services with a replacement and/or additional imaging service, and are unable to reach the ordering professional for a new order as described in Chapter 15, sections 80.6.2–4 of the Medicare BPM, are to append to the Medicare claim for the service(s) the AUC consultation information provided by the ordering professional specific to the original order.

ii. Extreme and Uncontrollable Circumstances Hardship Exception

In the CY 2019 PFS final rule, we describe extreme and uncontrollable circumstances to include disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems. We also explain these may include areas where events occur that have been designated by FEMA as a major disaster or a public health emergency declared by the Secretary. To further clarify, these circumstances are events that are entirely outside the control of the ordering professional that prevent the ordering professional from consulting AUC through a qualified CDSM. We believe the hardship criteria under this program are similar to other programs such as the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), particularly the flexibility that is given to clinicians to identify what they consider to be extreme and uncontrollable circumstances.

The PHE for COVID–19 has been in effect since January 27, 2020. Stakeholders have described challenges in continuing to prepare for the payment penalty phase of the AUC program due to resource reallocation resulting from the PHE. Some stakeholders have explained that all health technology projects unrelated to the PHE were halted, including projects that impact establishing or updating health IT systems that enable AUC consultation through qualified CDSMs.

Stakeholders have also indicated that human resources were reallocated to focus on responding to the PHE. Additionally, we recognize that practitioners have been heavily impacted in their own practice of medicine to respond to the PHE and provide treatment to patients which may have prevented them from focusing on and participating in the educational and operations testing period to prepare for the payment penalty phase. While we are continuing to move forward in implementing the AUC program, we want to assure stakeholders that they may attest to a significant hardship under the AUC program due to extreme and uncontrollable circumstances due to the PHE for COVID–19, and such an attestation may be used as needed by ordering practitioners throughout the PHE. Furthermore, as the AUC program progresses into the payment penalty phase, self-attestation for a significant hardship exception will continue to be available for ordering professionals experiencing extreme and uncontrollable circumstances due to the PHE. We also recognize that ordering professionals may experience significant hardships related to or resulting from the PHE that extend beyond the date the PHE expires and note that AUC program exceptions will continue to be available for such significant hardships as defined at § 414.94(i)(3).

We received public comments on the extreme and uncontrollable significant hardship exception along with comments on other exceptions. The following is a summary of the comments we received and our responses.

Comment: Some commenters agreed with our clarification that the PHE for COVID–19 is a significant hardship and significant hardships due to the PHE may extend beyond the date the PHE expires. Another commenter agreed that the PHE for COVID–19 is a proper circumstance for an extreme and uncontrollable circumstance exception even after the start of the payment penalty phase of the AUC program if the PHE or effects of the PHE impact ordering professionals. Other commenters requested that CMS allow providers to use the extreme and uncontrollable circumstances exemption for at least one year following the start of the payment penalty phase because of the PHE.

Response: We appreciate the support of the commenters. As significant hardship exceptions under the AUC program are self-attested, we did not propose, and decline to specify time frame parameters around experiencing an extreme and uncontrollable

circumstances significant hardship due to the PHE for COVID–19.

Comment: One commenter requested that CMS harmonize the hardship exceptions with the Quality Payment Program (QPP) hardship exceptions and allow ordering professionals and furnishing professionals to annually attest to hardship rather than on every claim. One commenter stated that significant hardship exemptions should be included for furnishing professionals.

Response: As discussed in the CY 2019 PFS final rule, the AUC program requires real time reporting of information on the Medicare claims for payment purposes while the QPP is not a real time program, but instead uses data from prior performance years to determine status and potential payment adjustments in future years. We explained in that final rule that this difference along with the statutory differences between the programs necessitates a separate significant hardship exception approach and process for the AUC program. In that final rule, we further discuss that the real time self-attestation process (as opposed to a blanket exception for a predetermined period of time) ensures that clinicians have the ability and flexibility to use the significant hardships allowable under the program. We also noted that applying a blanket exception for a specific period of time for ordering professionals based on a single significant hardship attestation would introduce a level of complexity and burden to the process whereby furnishing professionals would need to keep track of which ordering professionals had attested to a significant hardship and over what applicable period of time every time an order is received and a claim is prepared, submitted and processed. We also note that the statute provides for significant hardships for ordering professionals for whom consultation with AUC would result in a significant hardship but the statute does not provide for significant hardships specific to furnishing professionals.

Comment: One commenter requested that, like QPP, the AUC program include an exception for new physicians for one year and for low volume of Medicare patients.

Response: As discussed in the CY 2019 PFS final rule, we do not have the authority to include exceptions to the AUC program beyond the scope of those specified in section 1834(q)(4)(C) of the Act. As explained in that final rule, we believe that significant hardships are reflective of situations that would impede clinicians from consulting AUC through a CDSM and we do not agree

that ordering professionals in practices with a low volume of Medicare patients would be impeded from consulting AUC. Similarly, we stated that we do not believe being a new physician would cause the act of consulting AUC to be particularly difficult or challenging for ordering professionals.

Comment: Two commenters requested exceptions for providers in value-based care models and two commenters requested exceptions for physicians and practices that are already taking on financial risks in advanced payment models (APMs).

Response: The statute does not except participants in certain types of models or initiatives from the AUC program requirements.

Comment: Several commenters requested CMS address how second opinions are to be handled under the AUC program. One commenter stated that it is important to exempt second opinions of already performed and interpreted imaging studies to prevent additional imaging, ensure timely access for patients and limit barriers to evaluation by subspecialty radiologists. Another commenter specifically requested guidance on whether a consulting professional must also consult AUC and how to indicate that consultation was performed particularly if it does not result in a new order and, when it does result in a new order, whether the consulting professional should order the second imaging service and whether the ordering professional must consult AUC a second time. One commenter specifically requested clarification around how the AUC requirements apply to second opinions and how orders that are placed contra-AUC for legitimate clinical reasons are to be identified.

Response: We believe the AUC consultation and reporting requirements apply to second opinions in the same way they apply to original patient assessments and resulting orders for advanced diagnostic imaging services. If an additional PC is submitted for an imaging services due to a second opinion, the AUC consultation information specific to the advanced diagnostic imaging services that was furnished (the original order) would be appended to the claim for the PC. If, based upon this second opinion, further tests must be ordered, they would require separate and additional AUC consultation as they are new/additional orders. We note that, as introduced by commenters, second opinions are different from modified orders, so if new or additional orders result from the second opinion review, these would be new, subsequent orders and thus be

subject to the AUC program requirements as such. We expect second opinions to proceed as they normally would, but with the inclusion of AUC consultation and subsequent reporting on the Medicare claims for and new or additional orders for advanced diagnostic imaging services. When reporting, the appropriate modifier indicating the outcome of the AUC consultation should be appended to the claim, even if the order ultimately placed would not adhere to the AUC consulted albeit for legitimate clinical reasons.

Comment: Some commenters asked if the AUC requirements apply to imaging ordered pursuant to a clinical trial protocol, what modifier should be appended and how to indicate on the claim that the service was pursuant to a clinical trial. Commenters also requested that imaging services performed as part of a clinical trial be excluded from the AUC program and that a separate HCPCS modifier be established to identify such claims.

Response: As discussed above in section III.F.3.c. of this final rule, section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements and these exceptions are codified in our regulations in § 414.94(h)(1)(i). We disagree that advanced diagnostic imaging services furnished pursuant to or as a part of a clinical trial qualify for an exception as specified in the statute and regulations and described above in section III.F.3.c. of this final rule; therefore, we are unable to exclude or except claims for these imaging services. The AUC consultation information relevant to the imaging service that is ordered should be appended on the claim to accurately communicate information about the consultation. Because these services are subject to the AUC program requirements, we do not see a need to establish a separate modifier to identify these services. We note that claims for many clinical trials covered by Medicare must include the national clinical trial (NCT) identifier number, HCPCS modifiers Q0 (zero) or Q1 (one) and also ICD-10 diagnosis code Z00.6, so there are other ways to track claims submitted as part of clinical trials if necessary.

b. Claims Processing

As we move ahead to implement the payment penalty phase of this program, we must address additional operational and administrative issues. We explain these issues here, and our assessments and proposals for addressing them. We solicited comments on whether additional scenarios require our

consideration, and whether the proposed solutions adequately address issues raised by stakeholders. We solicited any additional information stakeholders may offer to assist us in developing claims processing system edits or other measures to ensure that only appropriate claims are subject to AUC claims processing edits. The AUC program will be fully implemented when we have the necessary edits established in the claims processing system and we begin using those edits to deny Medicare claims that fail to report the required AUC consultation information. The identification of claims that are or are not subject to the Medicare AUC Program must be precise to avoid inadvertently denying claims that should be paid. Because implementation of this program establishes edits for advanced diagnostic imaging claims, the inadvertent denial of claims would disproportionately impact radiologists, HOPDs and freestanding imaging centers. Also, as we have noted previously, the AUC program is unique in that the burden of consulting AUC and providing AUC consultation information to the furnishing professional falls on the ordering professional, yet the claims that are denied for failing to report AUC consultation information are for services furnished and billed by the professionals and facilities that furnish advance diagnostic imaging.

Two main Medicare claim types are subject to claims processing edits in the AUC program. These are the CMS-1500 and its electronic equivalent (referred to here as the practitioner claim) submitted by physicians and practitioners, ASCs, and IDTFs, and the UB-04, also called the CMS-1450, (referred to here as the institutional claim) submitted by HOPDs and on-campus and off-campus provider-based departments. These claim types differ in the data elements they contain; therefore, claims processing edits will not be identical across claim types.

We have already issued partial claims processing instructions (CR11268, Transmittal 2404)⁹⁰ to support the educational and operations testing period. We established HCPCS Level III G-codes for furnishing professionals to report which CDSM was consulted on a separate claim line. We also established HCPCS modifiers for furnishing professionals to report adherence, non-adherence and not applicable AUC consultation responses on the same claim line as the advanced diagnostic

⁹⁰ <https://www.cms.gov/files/document/r2404otn.pdf>.

imaging HCPCS code. We established additional HCPCS modifiers for furnishing professionals to report situations in which the ordering professional is not required to consult AUC, which are also reported on the same claim line as the advanced diagnostic imaging HCPCS code. Both G-codes and modifiers are applicable to practitioner and institutional claims. We also established a procedure code list that identifies the advanced diagnostic imaging codes that are subject to the AUC program. Based on a review of CY 2020 Medicare claims (noting for readers that during this year the AUC program was only in the education and operations testing phase with no payment penalties), we estimate between 9–10 percent of all claims subject to the AUC program reported information sufficient to be considered compliant with the program. This means that 90–91 percent of claims would not be considered compliant with AUC program requirements because they do not include either the required AUC consultation information (including the ordering professional NPI, G-code identifying the qualified CDSM consulted, and the modifier specifying the appropriateness of the order) or a modifier indicating an applicable exception to the AUC consultation information reporting requirements. In other words, if the claims processing systems edits had been in place for the payment penalty phase, only 9–10 percent of claims subject to the AUC program would have been paid as opposed to being denied or rejected. An additional 6–7 percent of claims subject to the AUC program included some relevant information, which demonstrates an awareness of the AUC program among these billing entities; but the claims did not include all of the necessary AUC consultation information that will ultimately be required for the claim to be paid.

i. Ordering Professional NPI

There are locations on both the practitioner and institutional claim types to report the NPI of the ordering professional. The institutional claim uses the K3 segment and the practitioner claim uses the referring professional field. However, to fully implement the AUC program, we must establish a claims processing edit to require these fields to be populated on all advanced diagnostic imaging claims subject to the AUC program.

In addition, there currently are situations in which multiple advanced diagnostic imaging services ordered by more than one ordering professional may be reported on a single claim. This

would not be workable for purposes of reporting AUC consultation information because the referring professional field is reported at the claim-level and not at the claim line- or service-level for professional claims. Therefore, the furnishing professional will need to submit separate claims for the services ordered by each referring or ordering professional. In other words, only one ordering professional can be reported per claim.

We received comments on this discussion. The following is a summary of the comments we received and our responses.

Comment: One commenter, referencing different sections of the 837 professional claim, requested confirmation that practitioner claims are unable to accommodate line-level identification of the ordering professional NPI as discussed above. This commenter stated that while the referring professional is a claim level element in ASC 5010 837 Professional Claim Loop 2310A, there is also a line-item element for referring professional in Loop 2420F. This commenter requested further clarification in terminology used by CMS, noting that there are different fields on the claim forms for “ordering” and “referring” professionals and whether CMS is placing limitations on the “ordering professional” or “referring professional” elements and how that dictates claims be split. This commenter requested CMS be completely clear on which fields are to be populated with the NPI of the practitioner that ordered the service and whether services for one beneficiary ordered by more than one practitioner must be split into separate claims.

Response: Upon further review of the 837P form, we agree that the practitioner who orders the advanced diagnostic imaging service can be identified at the line level and we will proceed with implementation accordingly. We expect this means the 837P claims will not be required to be submitted separately for each practitioner who orders advanced diagnostic imaging services (the “ordering professional” as defined under the AUC program). We will continue to evaluate which line-item field is most appropriate to populate (the ordering or referring professional fields on the claim).

Comment: One commenter stated that one ordering clinician per claim is not overly burdensome in most situations and another commenter noted that splitting claims is not ideal, but can be done and should not hold up the AUC program. This commenter stated that a significant amount of manual

intervention will likely be required. One commenter stated that submitting separate claims to accommodate different ordering professionals will be difficult because their current system groups ordering professional encounters for the same date of service on the same institutional claim. This commenter explained that separate claims will require separate registrations which is more burdensome for registration staff and may dissatisfy patients. Furthermore, this commenter stated that two or more account numbers with the same date of service may increase error for documentation and charging. This commenter asked if Medicare will be able to process two separate ordering professional claims with the same date of service.

Response: As noted in the response above, we believe the 837P claim can identify different practitioners that order advanced diagnostic imaging services at the line level so splitting claims will not be necessary, which will also minimize burden. As we proceed with establishing claims processing instructions for the payment penalty phase of the program, we will continue to explore opportunities to minimize burden.

After consideration of public comments, we will move forward with developing claims processing instructions that allow more than one practitioner that orders advanced diagnostic imaging services to be reported on the practitioner claim.

ii. Critical Access Hospitals

As discussed in the CY 2018 PFS final rule with comment period (82 FR 53192), advanced diagnostic imaging services furnished in an outpatient department of a critical access hospital (CAH) are not subject to the AUC program because, in accordance with section 1833(q)(1)(D) of the Act, a CAH is not an applicable setting under the program. Therefore, we must identify these advanced diagnostic imaging services and allow them to bypass the AUC program claims processing edits. For institutional claims, we intend to apply the AUC program claims processing edits to type of bill 13x, which is used only for outpatient hospital settings. CAHs submit outpatient claims using type of bill 85x, rather than type of bill 13x.

In the CY 2019 PFS final rule (83 FR 59694), we further explained that because section 1834(q)(4)(B) of the Act clearly includes all claims paid under applicable payment systems without exclusion, the claims from both furnishing professionals and facilities must include AUC consultation

information. We revised our regulation at § 414.94(k) to specify that AUC consultation information must be reported on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. Prior to this revision, § 414.94(k) required furnishing professionals to report AUC consultation on the claim, without also specifying that facility claims must include the AUC consultation information. In the CY 2019 PFS final rule, we explained that the AUC consultation information would be included on the practitioner's claim for the PC of the service and on the provider's or supplier's claim for the facility portion or TC of the service. Under § 414.94(k), the requirement to report AUC consultation information on the claim applies to both the PC and TC of the imaging services that are furnished in an applicable setting and paid under an applicable payment system. Section 1834(q)(4)(B) of the Act further specifies that the requirement to report AUC consultation information is specific to claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. We believe that all claims for advanced diagnostic imaging services, both the PC and TC, must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. However, if advanced diagnostic imaging services are not entirely furnished in an applicable setting, we believe that neither the PC nor TC claim should be required to include AUC consultation information. This ensures consistent application of the AUC consultation requirements across claims submitted for advanced diagnostic imaging services even when the PC and TC components of the service are furnished by different furnishing professionals. As such, we proposed that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting will not be subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. If a physician or practitioner submits a claim for the PC of an advanced imaging service for which the TC was performed as an outpatient CAH service, there currently is not a systems-based way for us to recognize that the TC of the service was

furnished by a CAH. Place of service codes reported on practitioner claims are not specific enough. We have not yet identified a way to segregate these claims and automatically allow them to bypass AUC program claims processing edits. Therefore, as discussed below, we proposed to establish a separate HCPCS modifier that will be used to identify practitioner claims for advanced diagnostic imaging services that are not subject to the AUC program and that are not otherwise identified using the other AUC program modifiers designated to identify specific situations where the claims are not subject to the AUC program.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the proposal that the PC for an advanced diagnostic imaging service for which the TC was furnished by a CAH would also not require AUC consultation information appended to the claim. One commenter also supported applying this proposal for any other non-applicable sites. One commenter expressed support for excluding services when the TC is not furnished in an applicable setting. One commenter agreed with the proposal to identify these situations using a modifier on the claim.

Response: We appreciate the comments. We prefer to automate the identification of these claims whenever possible and will continue to search for a mechanism. For example, we recently determined that a CAH can be identified in the CCN by a number 1 in third position and a number 3 in the fourth position. We will explore whether we can automate an edit in the claims processing system to identify CAH claims using the CCN.

Comment: Some commenters urged CMS to extend the exemption to ordering professionals that order advanced diagnostic imaging services in CAHs as CAHs have limited resources.

Response: As discussed in section III.F.3.c. of this final rule, section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements and these exceptions are codified in our regulations in § 414.94(h)(1)(i). We disagree that ordering professionals that order advanced diagnostic imaging services in a CAH qualify for an exception as specified in the statute and regulations and described above in section III.F.3.c. of this final rule.

Comment: Two commenters stated that the MH modifier does not describe this situation so a new modifier would

need to be created. One of these commenters further noted that using modifier MH for CAH related claims will impact data integrity by combining CAH providers with those that do not provide AUC consultation information.

Response: We appreciate this comment and further discuss modifier MH in section III.F.4.b.viii. of this final rule.

After consideration of public comments, we are finalizing this proposal that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting not be subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. We are also finalizing the proposal to use a modifier to identify practitioner claims for advanced diagnostic imaging services that are not subject to the AUC program, like those submitted for advanced diagnostic imaging services furnished in a CAH, and that are not otherwise identified using the other AUC program modifiers designated to identify specific situations where the claims are not subject to the AUC program. We further discuss this modifier in section III.F.4.b.viii. of this final rule.

iii. Maryland Total Cost of Care Model

Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for which AUC consultation and reporting requirements apply are the PFS, the hospital OPPS and the ASC payment system. We define applicable payment system consistent with statute at § 414.94(b) and, as noted above, require AUC consultation information to be reported on Medicare claims for advanced diagnostic imaging services, both the PC and TC, furnished in an applicable setting and paid under an applicable payment system at § 414.94(k). Section 1834(q)(4)(B) of the Act specifies that the requirement to report AUC consultation information is specific to claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. We believe that all claims for the advanced diagnostic imaging services, both the PC and TC, must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. Therefore, if both the PC and TC for advanced diagnostic imaging services are not paid under an applicable payment system, neither the PC nor TC claim is required to include

AUC consultation information. This ensures consistent application of the AUC consultation requirements across claims submitted for advanced diagnostic imaging services even when the PC and TC components of the service are furnished by different furnishing professionals. Similar to claims for the PC of services for which the TC is furnished outside of an applicable setting, and because both practitioner and institutional claims are subject to the AUC program as discussed above, when the practitioner or institutional claim for the advanced imaging service is not subject to the AUC program (for example, payment is not made under an applicable payment system), the corresponding practitioner or institutional claim for the same imaging service is also not subject to the AUC program.

Stakeholders alerted CMS to concerns about whether advanced diagnostic imaging services furnished in hospitals participating in the Maryland Total Cost of Care Model would be subject to the AUC program. We appreciated that this was brought to our attention and we solicited comments on other models. Advanced diagnostic imaging services furnished in outpatient departments of Maryland hospitals that participate in the Hospital Payment Program within the Maryland Total Cost of Care Model are not subject to the AUC program because these services are not paid under an applicable payment system (Maryland hospitals that receive payments under the Hospital Payment Program within the Maryland Total Cost of Care Model are not paid under the OPPS). Because these services are not subject to the AUC program requirements when furnished in a hospital paid under the Hospital Payment Program within the Maryland Total Cost of Care Model, as opposed to an applicable payment system, we propose that the PCs of these advanced diagnostic imaging services, when billed separately, are also not required to include AUC consultation information. We believe we can identify all institutional claims from a hospital that is paid under the Hospital Payment Program within the Maryland Total Cost of Care Model based on their CMS Certification Number (CCN) and allow those claims to bypass AUC program claims processing edits. We understand that when the TC and PC of advanced diagnostic imaging services are billed separately, the professional claim must identify in box 32 the location where the TC of the imaging service was furnished to the patient. Therefore, we believe we will have the ability to

identify situations in which the imaging service was furnished in a hospital that is paid under the Hospital Payment Program within the Maryland Total Cost of Care Model and exclude those claims from being subject to AUC program claims processing edits. We believe this can be accomplished by using the CCN and will continue to work to determine if a list of CCNs can be used as the source of our edits in addition to determining the frequency that the list will be updated.

Note that advanced diagnostic imaging services furnished in applicable settings in the State of Maryland and paid under an applicable payment system are subject to the AUC program—the above discussion applies only to the outpatient departments of hospitals that are paid under the Hospital Payment Program within the Maryland Total Cost of Care Model.

We received comments on the Maryland Total Cost of Care Model related proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed concerns with excluding Maryland outpatient hospital departments under the Maryland Total Cost of Care Model from the AUC program requirements and instead recommended that all Maryland ordering professionals be excluded. The commenter stated that excluding outpatient hospital departments under the model will have negative unintended consequences. These include acting as an incentive for ordering professionals to send Medicare patients to hospitals instead of non-hospital entities like imaging centers and IDTFs creating a major competitive disadvantage for imaging centers, IDTFs and other non-hospital imaging providers in Maryland. The commenter stated that it may disrupt existing referral patterns and continuity of care, is likely to increase cost to Medicare and patients through higher out of pocket expenses at high priced hospital facilities, will inconvenience patients through longer travel times, scheduling delays resulting from higher demand for hospital based imaging and limited access due to COVID and related staffing shortages. The commenter requested that if Maryland Total Cost of Care Model participating outpatient departments are excluded from the AUC program, CMS explore ways to restore competitive balance between Maryland outpatient departments and non-hospital imaging providers like giving ordering professionals more flexibility in meeting AUC consultation requirements and/or making AUC a required performance metric under the

Maryland model. The commenter further requested CMS clarify if hospital-owned imaging centers, whether on-campus or off-campus, that are paid for advanced diagnostic imaging services according to the PFS or OPPS, regardless of provider tax ID number used for billing, are still subject to the AUC program.

Response: We appreciate this comment and understand the concerns expressed, however we are unable to modify the AUC requirements and applicability in the State of Maryland given the statutory provisions that AUC consultation and reporting is required for advanced diagnostic imaging services furnished in an applicable setting and paid for under an applicable payment system. Since services furnished under the Maryland Total Cost of Care Model are not paid under an applicable payment system, the advanced diagnostic imaging services furnished under the model are not subject to the program requirements. We are unable to create an exception for other locations or providers in Maryland to offset the potential impact of the model on settings or providers that are not included in the model. The AUC program requirements apply to advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system as specified in § 414.94 without exclusion of sites based on ownership or the provider tax ID used for billing.

After consideration of public comments, we will continue to work to set up claims processing edits using the CCN in box 32 to identify advanced diagnostic imaging services furnished under the Maryland Total Cost of Care Model, the claims for which, as discussed above, are not subject to the AUC program requirements.

iv. Inpatients Converted to Outpatients

While uncommon, there are situations in which a beneficiary's hospital inpatient status is changed to outpatient. Certain criteria must be met for this to occur and, if met, condition code 44 (inpatient admission changed to outpatient) is appended to the institutional claim (<https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r299cp.pdf>). We proposed to allow institutional claims with condition code 44 to bypass AUC claims processing edits. We made this proposal because, at the time advanced diagnostic imaging services were ordered and furnished, they were ordered for and furnished to a beneficiary who was in inpatient status. As such, the AUC consultation

requirement would not have applied at that time. We believe that any professional claims would include place of service code 21 (inpatient hospital) since the expectation, until just prior to discharge, would be that the patient is in an inpatient status. We expect less than half of one percent of claims will include condition code 44.

We received comments on our proposal to allow institutional claims with condition code 44 to bypass AUC claims processing edits. The following is a summary of the comments we received and our responses.

Comment: Some commenters agreed with this proposal. Two commenters supported the proposal but noted that not all patients moved from inpatient to outpatient will be captured with condition code 44 so CMS should create an exception for any inpatient order for advanced diagnostic imaging services furnished within a short period after the inpatient discharge and use a new modifier for these instances where inpatient imaging orders are performed in the outpatient setting shortly after discharge. One commenter requested that in addition to excepting “inpatient to outpatient”/condition code 44 claims, CMS should also except inpatient part A claims that are self-denied or denied by an auditor and then rebilled to part B, usually with a 131 or 121 claim since imaging services were furnished to an inpatient at the time.

Response: We appreciate the comments and disagree that a modifier is needed to capture relevant claims. In section III.F.4.b.ix. of this final rule, we discuss proposals around what type of bill would be subject to the AUC program edits and do not include type of bill 121 which is used for Medicare Part A/B rebillings for services that occurred during the inpatient period. Type of bill 131 is an outpatient bill type and is included in the type of bill to which we proposed, and are finalizing, to limit claims processing edits. As discussed below, we are finalizing this proposal.

After consideration of public comments, we are finalizing the proposal to allow institutional claims with condition code 44 to bypass AUC claims processing edits.

v. Deny or Return Claims That Fail AUC Claims Processing Edits

As discussed above, claims that do not properly include AUC consultation information will not be paid once we fully implement the AUC claims processing edits. We are considering whether claims that do not pass the AUC claims processing edits, and therefore, will not be paid, should be

initially returned to the health care provider so they can be corrected and resubmitted, or should be denied so they can be appealed. On one hand, we expect there will be some errors in reporting AUC consultation information on claims, especially early on, and health care providers might find it helpful to have the opportunity to correct claims. However, there may be situations in which the health care provider would prefer the claim be denied so they have an earlier opportunity to appeal. We requested comments to help us better understand which path would be most appropriate once we fully implement the AUC program claims edits. Additionally, we requested comments on whether the payment penalty phase should begin first with returning claims and then transition to denying claims after a period of time, which may be helpful to furnishing professionals and facilities as they become more proficient in submitting claims under the AUC program.

We received public comments on which path would be most appropriate once we fully implement the AUC program claims edits and whether the payment penalty phase should begin first with returning claims and then transition to denying claims after a period of time. The following is a summary of the comments we received and our responses.

Comment: Some commenters recommended that claims be returned for correction instead of being denied. Some of these commenters noted that returning claims affords practitioners the opportunity to correct and resubmit which is a faster, easier and less costly process than denying and appealing. Other commenters suggested claims be returned at least initially for similar reasons. Two of these commenters suggested returning claims for the first year of the payment penalty phase and then transition to denials, one supported transitioning to denials but did not identify a timeframe within which to transition, and two commenters suggested revisiting the approach at some point in the future to determine if it should be revised. One commenter recommended that CMS should allow for correction of claims without complete information on the front-end by indicating the claim cannot be accepted for processing until it contains necessary information. One commenter stated that if CMS decides to deny claims, the denials should be for the line-item if AUC information is not present instead of denying the whole claim. One commenter suggested that instead of deciding whether to deny or

return claims, CMS should ensure the program does not result in substantial number of claims submission issues for furnishing provider claims.

Response: We appreciate the recommendations and perspectives shared by commenters and assure commenters that we working to establish claims processing solutions amenable to the practitioners and providers impacted by this program to the best of our ability given the constraints of the claims processing systems and specifications set forth in statute.

Comment: Two commenters requested CMS clearly outline the claim denial process and how it pertains to ordering and furnishing providers. One commenter requested further detail and elaboration of criteria used in claims processing and auditing as soon as possible so institutions can incorporate internal review prior to claims submissions.

Response: We remind readers that the reporting requirements are specific to the furnishing professionals as AUC consultation information is required on the claim for the advanced diagnostic imaging service. Since the ordering professional, unless they are also the furnishing professional, does not submit a claim for the advanced diagnostic imaging service, the claim denial process would not impact them. As we proceed through the process of establishing claims processing systems edits and instructions, we will post those documents on the AUC website: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program>.

After consideration of public comments, we agree that returning claims for correction and resubmission when the payment penalty phase begins would be most appropriate. If needed, we may revisit whether claims denials are appropriate at some point in the future once practitioners become more comfortable with the claims processing requirements.

vi. Medicare as a Secondary Payer

We understand based on feedback from stakeholders that, in some EHRs, the primary payer information is readily available and known to the ordering professional; however, secondary payer information typically is not available. Additionally, it is possible that when Medicare is the secondary payer that no Medicare payment would be made at all after the primary payer makes payment. Medicare is reported as the secondary payer for approximately 1.5 percent of advanced diagnostic imaging services

that are subject to the AUC program. Because the secondary payer information for a patient generally is not available to the ordering professional, and because no Medicare payment may be involved at all when Medicare is the secondary payer, we proposed to exclude claims that identify Medicare as the secondary payer from application of the AUC consultation and reporting requirements. Specifically, we proposed to allow claims that identify Medicare as the secondary payer (using block 1 or the electronic equivalent of the practitioner claims and using FL 50/51 or the electronic equivalent of institutional claims) to bypass the AUC program claims processing edits.

We received public comments on excluding claims that identify Medicare as the secondary payer from application of the AUC consultation and reporting requirements. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to exclude claims that identify Medicare as the secondary payer from the AUC consultation and reporting requirements. Two commenters stated that if this proposal is implemented, it would change how primary and secondary payer information is captured in health information technology (HIT) so HIT systems would need sufficient advance notice to update accordingly. One commenter specified that HIT systems would need a minimum of 18 months to scope, develop, test and implement new requirements.

Response: We appreciate the comments and will work to issue claims processing instructions as expeditiously as possible.

Comment: One commenter asked if Medicare Managed Care claims require AUC consultation information.

Response: The AUC program requirements under our regulations are specific to fee-for-service Medicare, so Medicare Advantage organizations (MAOs) are not required to follow the AUC program requirements, and the requirements do not apply to Medicaid. However, MAOs might require their contracted providers to follow Medicare AUC program procedures, so you would need to contact the MAOs (and any other types of plans) for more information about their requirements specific to AUC.

After consideration of public comments, we are finalizing as proposed to allow claims that identify Medicare as the secondary payer (using block 1 or the electronic equivalent of the practitioner claims and using FL 50/51 or the electronic equivalent of

institutional claims) to bypass the AUC program claims processing edits.

vii. Date of Service and Date of Order

We will specify a start date for the AUC program claims processing edits to take effect. Medicare claims include a date of service but do not allow for the date of an imaging order to be recorded. Because we cannot identify the order date for an advanced imaging service based on claims, we proposed that the AUC program claims processing edits for the payment penalty phase will be applicable for advanced imaging services furnished on or after the effective date of the claims edits. For imaging services ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, the furnishing professional would apply the separate HCPCS modifier discussed in section III.F.4.b.ii. (Critical Access Hospitals) of this final rule to indicate that the claim is not subject to the AUC claims processing edits.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters disagreed with this proposal and instead recommended that for services ordered prior to the penalty phase but furnished after it begins, CMS should have a grace period within the penalty phase for these services which would eliminate the burden associated with returning claims. This commenter suggested soft edits to establish the end of the grace period based on a decrease in potential returns. Some commenters supported this proposal and agreed with denoting these claims with a separate modifier.

Response: Because the time over which advanced diagnostic imaging services are ordered for patients with chronic or ongoing conditions necessitating repeat imaging is different for each patient, we disagree that establishing a grace period to account for these situations is a viable option. We believe allowing these claims to instead bypass edits based on the presence of a modifier is more appropriate, particularly since all other advanced diagnostic imaging services will be subject to payment penalties when the payment penalty phase begins. This approach would essentially extend the educational and operations testing period further.

After consideration of public comments, we are finalizing as proposed our proposal to identify claims for imaging services ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, using the

separate HCPCS modifier we will create to identify claims that are not subject to AUC claims processing edits.

viii. HCPCS Modifiers

We established two primary sets of HCPCS modifiers for this program. In the proposed rule we erroneously stated that the first set of modifiers, which report whether the imaging service adheres to the AUC consulted (modifier ME), does not adhere to the AUC (modifier MF), or the qualified CDSM does not contain AUC that applies to the order (modifier MG), is to be included on the same claim line as the G-code identifying the CDSM that was consulted. This is incorrect and we are correcting this mistake with the following revised description of modifier placement, consistent with the previously released MLN Matters article 11268. The first set, modifiers ME, MF and MG, is to be included on the same claim line as the CPT code for the advanced diagnostic imaging service. We intend for these modifiers to continue to be used when the program enters the payment penalty phase. Additionally, reporting of these modifiers should be limited to one per qualified CDSM G-code (listed on a separate claim line) since these modifiers are mutually exclusive.

The second set of HCPCS modifiers is available for use when the ordering professional does not consult a qualified CDSM. On these claims, providers would not add a G-code for a CDSM because a consultation did not take place, and the HCPCS modifier would be included on the same line as the procedure code for the advanced diagnostic imaging service that was furnished. These HCPCS modifiers include the three that were created to describe significant hardship exceptions (insufficient internet access (modifier MB), EHR or CDSM vendor issues (modifier MC) and extreme and uncontrollable circumstances (modifier MD)). Additionally, section 1834(q)(4)(C) of the Act includes an exception for services ordered for an individual with an emergency medical condition and modifier MA is available to identify claims for patients with a suspected or confirmed emergency medical condition. This set of codes is mutually exclusive and we expect only one to be reported per procedure code-level claim line.

Modifier QQ was created for use during the voluntary period, before more detailed modifiers and codes were created, to indicate that an ordering professional consulted a qualified CDSM for the service and related AUC consultation information was provided

to the furnishing professional. The descriptor for this code explains that the ordering professional consulted a qualified CDSM for this service and the related information was provided to the furnishing professional. Modifier QQ continues to be available for use through the educational and operations testing period, but we intend to end the use of that modifier and not carry it forward into the payment penalty phase since we have established and will require the use of distinct modifiers to communicate specific AUC consultation information.

Modifier MH was created for use during the educational and operations testing phase to identify claims for which AUC consultation information was not provided to the furnishing professional and furnishing facility. When the AUC program enters the payment penalty phase, we will no longer have a need for this modifier because claims will be required to include AUC consultation information or indicate a reason the information is not required in order to avoid AUC program claims processing edits. Beginning for services furnished on and after the effective date of the AUC program claims processing edits, we proposed to redefine modifier MH to describe situations in which the ordering professional is not required to consult AUC and the claim is not required to report AUC consultation information. For example, we proposed to repurpose modifier MH to be used in the scenarios described in sections III.F.4.b.ii. (Critical Access Hospitals), III.F.4.b.iii (Maryland Total Cost of Care Model) if other options to identify claims are not feasible, and III.F.4.b.vii. (Date of Service and Date of Order) of this final rule as those scenarios would fall outside the scope of the AUC program requirements.

We received comments on the modifier discussion and proposals. The following is a summary of the comments we received and our responses.

Comment: Two commenters requested clarification on where the modifiers are to be placed on the claim. They noted that the proposed rule states that the modifier should be placed on the same line as the G-code denoting which qualified CDSM was consulted, however prior guidance in MLN Matters article 11268 states that the modifier should be placed on the same line as the CPT code for the imaging service.

Response: Thank you for bringing this to our attention and we apologize for the confusion. The description in the proposed rule was incorrect and has been revised in this final rule to be consistent with the previously

communicated instructions in MLN Matters article 11268.

Comment: One commenter agreed with the proposed modifier clarifications. Three commenters supported the proposal to end the use of modifier QQ when the payment penalty phase of the program begins.

Response: We appreciate the comments.

Comment: Several commenters requested more clarification around the use of modifier MA. One commenter asked if MA can only be used in the emergency department and another commenter asked if MA applies to EMTALA patients generally or only to patients with certain conditions. One commenter requested more specific information including guidelines for accurate and appropriate use of modifier MA to avoid overuse. Another commenter requested that CMS confirm modifier MA includes suspected or confirmed emergency medical conditions and recommended adding “suspected or confirmed” to the regulatory text. One commenter requested that CMS ensure this exception accounts for the time-sensitive evaluation needs of emergency patients.

Response: We have addressed and provided clarification on the emergency services exception, denoted with modifier MA, in notice and comment rulemaking in prior years. The statute and regulations do not limit the use of this exception, and thus modifier MA, to emergency department settings. The exception, as specified in both statute and regulation, is for applicable imaging services for individuals with an emergency medical condition, which the statute defines with a cross reference to section 1867(e)(1) of the Act. The exception may be used consistent with the regulations and additional clarification as discussed in prior rulemaking. Most recently, in the CY 2019 PFS final rule (83 FR 59699), which reiterated clarifications from the CY 2017 PFS final rule, we reminded readers that we agree that exceptions granted for an individual with an emergency medical condition include instances where an emergency medical condition is suspected, but not yet confirmed. We further stated that this may include, for example, instances of severe pain or severe allergic reactions. In these instances, the exception is applicable even if it is determined later that the patient did not in fact have an emergency medical condition. Given the clarifications previously communicated through rulemaking and the existing description for modifier MA, we disagree that the regulatory text for the

emergency services exception requires modification or further clarification.

Comment: One commenter asked what modifier is to be used for patients in the emergency department who do not qualify for the emergency services exception, but whose insurance is unknown when treated (as hospitals do not collect insurance information prior to emergency department medical screening), and therefore, a CDSM is not triggered. Another commenter requested that all emergency department visits be excluded since hospitals approach every patient as if they have an emergency medical condition thus requiring AUC consultations for emergency room patients without an emergency medical condition causes confusion and inconsistent practices within the emergency department.

Response: Because the statute explicitly includes the emergency department as an applicable setting under the AUC program, we are unable to categorically exclude all advanced diagnostic imaging services furnished in the emergency department, including those furnished to patients whose insurance is unknown at the time of treatment.

Comment: One commenter asked whether, and if so, how to report low acuity scores from CDSM consultations and whether low acuity scores will be reimbursed. Another commenter requested CMS clarify if claims with modifier MF or MG will be denied during the penalty phase.

Response: We believe the commenter asking about low acuity scores is referring to consultations where the order for the imaging service would not adhere to the AUC consulted (modifier MF) and are responding under this assumption. The statute specifies that, in order for a claim to be paid, information about the appropriateness of the ordered service is to be included on the claim. This reflects the certification or documentation qualified CDSMs are required to generate at the time of order under § 414.94(g)(1)(vi) when an ordering professional consults AUC and includes whether the service would adhere to the AUC consulted, whether the service would not adhere to the AUC consulted and whether the AUC consulted was not applicable to the service. As such, both modifier MF or MG may be appended to the claim to meet this requirement and the inclusion of these modifiers would not cause the claim for the service to be denied during the payment penalty phase.

Comment: We received many comments on our proposals for modifier MH. Two commenters supported the proposals to repurpose modifier MH for

use in situations in which the ordering professional is not required to consult AUC and the claim is not required to report AUC consultation information when other modifiers do not apply and claims system edits cannot automatically exclude the claims. Two commenters recommended repurposing modifier QQ instead of MH and four commenters requested modifier MH be maintained and CMS instead create a separate modifier for these scenarios. Commenters cited a variety of reasons for their disagreement with this proposal. Other commenters requested CMS maintain modifier MH unchanged because it will continue to be needed to identify situations when the ordering professional does not consult or provide AUC information to the furnishing professional. Some commenters noted that modifier MH is needed to identify outliers for the prior authorization component and two commenters stated that modifier MH was specifically created to indicate which ordering professionals were outliers so the Secretary can impose requirements to ensure the AUC program is followed. Still, other commenters stated that maintaining modifier MH is important to avoid imposing burden, like regulatory enforcement or follow-up with ordering professionals to track down AUC information, on furnishing professionals and facilities. Some commenters supported maintaining modifier MH to avoid delays or impediments to care. One commenter requested modifier MH be maintained at the start of the payment penalty phase as a failsafe to avoid delays in care if the ordering professional has not provided AUC consultation information. One commenter stated that requiring furnishing providers not to provide imaging services for non-compliant clinicians could create a dangerous situation where patients are unable to obtain medically necessary care. One commenter disagreed with repurposing MH because their systems have already been programmed for the current use of MH and significant resources would be needed to reprogram and train if MH is repurposed. Other commenters recommended creating a new modifier instead of repurposing modifier MH to avoid confusion and continued reporting of MH for its current use.

Response: To avoid confusion, CMS agrees with commenters that modifier MH should not be repurposed for use on claims as proposed. However, we do not agree with commenters requesting that modifier MH be maintained for current usage once the payment penalty phase begins because such a provision was not

specified in statute. The statute requires consultations to occur and for specific consultation information to be reported on the claim for the subsequently furnished imaging service in order for the claim to be paid. Unless an exception applies, Congress did not include a caveat excluding claims for services ordered by ordering professionals who either did not consult AUC or failed to provide consultation information to the furnishing professional from the statutory reporting requirements. As such, CMS does not have the authority to exclude these scenarios from the AUC program requirements. We also note that modifier MH was not created specifically to inform the outlier identification and prior authorization component of the program, as some commenters believe. Instead the other modifiers created to report the appropriateness of the consultation will be integral for identifying outlier ordering professionals as directed by the statute. Section 1834(q)(5)(B)(i) of the Act describes that the determination of an outlier ordering professional is to be based on low adherence to applicable AUC without mention of ordering professionals who fail to comply with the program requirements altogether. The statute does not provide a means for excusing or otherwise acknowledging these ordering professionals and we do not believe continued use of modifier MH during the payment penalty phase is within the parameters of the statute. Therefore, we intend to fully retire modifier MH when the payment penalty phase of the program begins.

Comment: One commenter asked if an ordering professional would be expected to do something on a pro forma basis to see if the order did adhere to applicable AUC guidelines and urged CMS to provide some grounding of good faith expectation for the furnishing provider to address missing AUC data to correct a claim when the AUC information was not originally provided. One commenter recommended that CMS create a document for furnishing professionals to use that would assist them in explaining to ordering professionals why they are required to consult AUC and provide that information with the order because there will be situations where the ordering professionals continue to fail to provide consultation information which causes the furnishing professionals to either provide the service for free or refuse to provide the service until the ordering professional provides necessary information.

Response: The AUC program requirements do not include provisions

for further or additional AUC consultations by ordering professionals. We recognize and have discussed the challenging nature of this program where the furnishing professional is subject to immediate penalty based on the actions (or lack thereof) of the ordering professional, whose behavior the furnishing professional is unable to control. Regardless, CMS is obligated to implement these statutory provisions and does not have the authority to modify or mitigate the requirements. We will continue to work on education and outreach and explore opportunities to update and expand our written outreach materials which may help to inform or remind ordering professionals of their responsibilities under the AUC program. Below, we summarize and respond to comments on education and outreach, as well as the general nature, utility and appropriateness of the AUC program.

Comment: One commenter stated that, similar to issues with patient relationship codes, automatic crossover to non-Medicare secondary payers results in denials from secondary insurance when AUC modifiers are sent. The claims are denied for invalid modifiers and CMS should find a way to strip out the modifiers before submission to secondary non-Medicare payers to reduce denials. Two commenters suggested CMS consider requesting a new value code to be used for facility reporting on a UB-04 when the entity is exempt. One commenter stated that CMS has not specified what G-codes or modifiers would be required for reporting and this approach has been rejected by the National Uniform Claim Committee (NUCC) and National Uniform Billing Committee (NUBC) which stated that G-codes and modifiers would be administratively burdensome. One commenter requested that CMS ensure there is a simplified tracking and reporting system.

Response: The modifiers the AUC program are valid HCPCS modifiers. Health Insurance Portability and Accountability Act of 1996 (HIPAA) transaction and code set regulations require all payers to accept all valid HCPCS modifiers. We will continue to consider all claims processing options. However, through extensive research and engagement with stakeholders including the NUCC and NUBC, we have not identified a more streamlined and less burdensome approach to capturing all statutorily required information on the Medicare claim in real time.

After consideration of public comments, we are finalizing our proposals and ending the use of modifier QQ when the payment penalty

phase begins. We will establish a new modifier to identify claims for services where the ordering professional is not required to consult AUC and the already established modifiers do not apply. This new modifier will apply when claims system edits cannot automatically exclude the claims to include the scenarios discussed in this final rule. Therefore, we are not finalizing our proposal to repurpose modifier MH for this use and instead, we intend to end the use of modifier MH when the payment penalty phase begins.

ix. Additional Claims Processing Information

Section 1834(q)(1)(D) of the Act specifies the applicable settings for the AUC program as a physician's office, a HOPD (including an emergency department), and ASC and any other provider-led outpatient setting determined appropriate by the Secretary. As discussed in the CY 2019 PFS final rule (83 FR 59690 and 59691), we added IDTFs to the definition of applicable setting at § 414.94(b) to the three applicable settings specified in statute because it is a provider-led outpatient setting in which advanced diagnostic imaging services are furnished by licensed, certified nonphysician personnel under appropriate physician supervision. To identify these settings through the Medicare claims system we evaluated type of bill and place of service codes to identify those aligned with applicable settings under the AUC program. For institutional claims, we proposed to limit AUC program claims processing edits to apply only to type of bill 13x (hospital outpatient). This claim type code encompasses the HOPD and the emergency department which represent all applicable settings under the program that will bill Medicare using institutional claims. For practitioner claims, we proposed to limit the edits to claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC). These place of service codes should encompass all applicable settings under the AUC program as defined at § 414.94(b). Because these type of bill and place of service codes reflect the applicable settings within which advanced diagnostic imaging services must be furnished to be subject to the AUC program requirements, we believe setting these parameters will allow us to more accurately pay claims while avoiding the need for other types of professionals and facilities to append modifiers to their claims.

We received public comments on limiting AUC program claims processing edits to apply only to institutional claims with type of bill 13x (hospital outpatient) and limiting the edits to professional claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC). The following is a summary of the comments we received and our responses.

Comment: One commenter noted that the proposals do not include claim types or place of service codes for IDTFs and requested that CMS clarify how claims processing edits would apply to IDTFs. Two commenters agreed with the place of service code proposals.

Response: We believe the institutional type of bill and professional claim place of service codes proposed above include all the applicable settings, including IDTFs, within which advanced diagnostic imaging services must be furnished to be subject to the AUC program requirements. We appreciate the comments.

After consideration of public comments, we are finalizing as proposed.

x. Claims Processing Summary

We have presented above some of the scenarios that CMS and stakeholders have identified as being potentially challenging or impracticable for application of the AUC program claims processing edits for purposes of the payment penalty phase. We requested feedback on whether additional scenarios require consideration and whether the proposed claims processing solutions will adequately address the issues raised. We also requested feedback on areas that stakeholders believe need more education to inform our ongoing outreach and education efforts. While much of the discussion is about identifying claims that are not subject to the AUC program, we note that physicians and other practitioners, or providers submitting claims for advanced imaging services that are not subject to the AUC program can voluntarily report AUC consultation information. We intend to allow those claims to process through the system. We requested commenters to provide additional information to assist us in developing edits that ensure only appropriate claims are subject to AUC claims processing edits.

c. Timing of Payment Penalties

We had previously announced in August 2020, via the CMS AUC website, that the education and operations

testing period of the AUC program would be extended through 2021 and the payment penalty phase will begin in January 2022. However, given the many complexities around the scope and application of AUC program claims processing edits, we believe that notice and comment rulemaking is the most appropriate means for us to discuss the implementation and claims processing issues, the start date of the payment penalty phase, and to obtain stakeholder feedback before subsequently finalizing a course of action in the final rule. This process will help ensure that we will appropriately identify claims for denial when the payment penalty phase of the program begins. In addition, we acknowledge the circumstances of physicians and other practitioners, and providers, due to the PHE for COVID-19 and that additional time may be needed to prepare for the payment penalty phase given the challenges and practice disruptions they have experienced while responding to the PHE.

The earliest that our claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. This is because it would not be possible for us to finalize implementation and claims processing plans in this final rule (typically published on or before November 1) and make those decisions effective any earlier than the 3rd calendar quarter of 2022. Implementing the types of claims processing edits necessary for this program generally requires a long lead time. However, we note that an effective date for the claims processing edits in October 2022 may be misaligned with typical annual updates to the systems used by the health care providers that are subject to the AUC program such as EHR, CDSM or claims submission systems. Therefore, we believe the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023.

While the above date takes into account technical system and programming concerns, it does not expressly take into the account the impact that the PHE for COVID-19 has had, and may yet have, on practitioners, providers and beneficiaries. Therefore, we proposed a flexible effective date for AUC program claims processing edits and payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19.

We acknowledge that the AUC program has been significantly delayed. We solicited public comment on this

proposal for the payment penalty phase to begin, and whether we have appropriately taken into account the PHE for COVID-19 and other factors. We recognize that some practitioners and institutions have already invested in qualified CDSMs, while others have had to redirect their resources during the PHE. We solicited information from the public on the state of readiness of practitioners, facilities, and EHR and CDSM vendors.

We received public comments on these proposals for the start of the payment penalty phase of the AUC program. The following is a summary of the comments we received and our responses.

Comment: One commenter requested no further delay to starting the program, and 94 commenters supported the proposal to begin the payment penalty of the program on the later of January 1, 2023 or the January 1 of the year after the year in which the PHE for COVID-19 ends. One commenter supported delaying the start of the payment penalty phase in 2022, but encouraged full implementation in 2023, another commenter requested CMS ensure full implementation in 2023. One commenter requested the payment penalty phase be delayed until 2024, while other commenters requested the payment penalty phase not begin until January 1, 2024 or January 1 of the year after the year in which the PHE ends, whichever is later. One of these commenters recommended this timeframe to ensure a testing year with all coding and billing requirements in place to allow time for HIT developers to make software changes to accommodate claims processing requirements. One commenter stated that physicians must be given at least 12 months to prepare for the penalty phase of the program once CMS makes public that all claims processing edits have been made and tested successfully. One commenter stressed the importance of ensuring physicians have the opportunity to adjust to the AUC program in a thoughtful and deliberate manner that would allow interoperability and the opportunity to develop solutions for data exchange between the ordering and furnishing professionals to leverage IT to reduce burden and suggested gradual implementation where claims are paid regardless of whether information is included on the claim. One commenter recommended using 2023 as an educational year where claims with errors are returned for correction without any financial penalty or denial due to AUC and implement the payment penalty phase no earlier than 2024.

Another commenter suggested that CMS continue voluntary participation where AUC consultation using a CDSM is not required and reimbursement is not contingent on documentation of consultation on the furnishing professional's claim.

Two commenters stated that they do not support the AUC program, one commenter requested that the AUC program should be abandoned and another commenter requested that the policy be revoked because it impacts timely access to care. Two commenters, citing implementation challenges and costs, stated that it is inconsistent with the best interests of Medicare and practices to divert resources from patient care to fully implement the AUC program. Another commenter asserted that imposing AUC requirements on ordering professionals for radiologists to be paid will be an "administrative nightmare." One commenter noted that hospitals are working on the implementation of AUC within their systems and the process has not been easy. Several commenters addressed the burden of the AUC program requesting that CMS ensure a least burdensome approach for implementation and work to alleviate burden and improve relevance of the program to physicians and Medicare. One commenter noted that, as designed, the AUC program does not foster the type of education about AUC that is necessary for AUC to have its intended effect.

Other commenters offered suggestions on further delays. Some commenters suggested the program not progress to the payment penalty phase until the vast majority of claims would meet the requirements to be paid. One commenter encouraged CMS to continue to analyze claims to ensure significantly higher percentage of claims report compliant AUC information and consider additional delays in the future. Another commenter also requested that CMS continue to monitor claims and consider deferring the payment penalty phase until at least 75 percent of claims for advanced diagnostic imaging services for the particular clinical specialty include adequate information for payment. Two commenters recommended CMS delay the program and solicit feedback on whether it requires updating before full implementation. Two commenters suggested additional delays and one commenter suggested indefinite delay. One commenter supported further delay in the absence of full program repeal with consideration for the overlap and duplicative burden with Medicare quality programs.

Commenters offered additional opinions on the AUC program in light of Medicare quality programs. Seven commenters asserted that the AUC program is unnecessary for APM participants because they are accountable for quality and cost of care, including incentives to reduce unnecessary imaging. These commenters noted that the AUC program does not consider quality, patient outcomes or other important factors more appropriately addressed in APMs. Two commenters requested CMS consider if a stand-alone AUC program is necessary or if requirements are redundant for QPP participants and one commenter requested CMS consider combining the AUC program with existing quality programs. One commenter suggested CMS consider aligning the goals and requirements of the AUC program with APMs and quality reporting programs to minimize burden and duplication. Other commenters requested CMS reduce burden of the AUC program since it has been superseded by the QPP. One commenter expressed disappointment at the absence of dialogue about how existing quality programs can be leveraged to encourage AUC consultation.

Some commenters suggested alternate options for enforcing compliance with AUC consultation requirements. Two commenters recommended allowing the use of qualified clinical data registries and another commenter recommended collecting requisite data directly from CDSMs. One commenter requested an annual attestation and CDSM audit approach and another suggested replacing claim-by-claim adjudication with provider attestation. Two commenters recommended CMS consider limiting AUC reporting to priority areas. Two commenters suggested revising the program so that payment penalties are paid by the referring physician and not the rendering provider. One commenter recommended CMS re-evaluate the foundational design of the program and the value it brings relative to potential burden and disruptions to clinical workflow. One commenter suggested a better solution than the AUC program would be to have rheumatology societies, orthopedic societies and primary care societies write best practice white papers, incorporate those guidelines into training and into a quality measure for those specialties.

Some commenters recommended that CMS engage with Congress to address the future of the AUC program. Two commenters requested the program be further delayed so CMS can work with

Congress to re-evaluate the feasibility and utility of the program and how appropriate use of imaging can be addressed through the QPP or other value-based initiatives and one commenter recommended CMS work with Congress to evaluate the validity of the AUC program given the significant time lapse between program inception and implementation. Some commenters also referenced the provision accompanying H.R. 4502 directing CMS to prepare a report to Congress on program implementation. Specifically, H. Rept. 117–96 “requests a report within 180 days of enactment of this Act on implementation of this program, including challenges and successes. In this report, CMS shall consider existing quality improvement programs and relevant models authorized under section 1115A of the Act and their influence on encouraging appropriate use of advanced diagnostic imaging. The Committee directs CMS to consult with stakeholders, including medical professional societies and developers of AUC and clinical guidelines, when formulating its report.”⁹¹ One commenter requested that CMS work expeditiously and in consultation with medical societies to fulfill the Congressional request once the appropriations bill is finalized and that the report include a comprehensive examination of existing and emerging quality improvement programs and relevant models being pursued by CMS Innovation Center and how they can influence appropriate use of advanced diagnostic imaging.

Many commenters requested that CMS use the additional time resulting from the proposed delay of the payment penalty phase to increase education and outreach efforts. One commenter shared that radiology practices are finding that ordering professionals are non-compliant and hospitals are non-responsive, thinking that they are not required to comply with the AUC program requirements so more education and webinars are needed. Commenters encouraged stakeholder engagement and identification of additional guidance and new flexibilities, significant education and technical assistance efforts, ongoing dialogue with providers and CDSM vendors to resolve remaining implementation issues and feedback on best practices. One commenter requested CMS provide regular program updates quarterly beginning at the end of the first quarter of 2022 on the status of implementation and the anticipated

payment penalty start date. One commenter stated that CMS initiate an education and outreach campaign akin to efforts for operationalizing the new Medicare Beneficiary Identifier. Several commenters requested CMS release claims information more frequently. One commenter requested quarterly claims data updates about AUC reporting uptake and common errors. One commenter requested that CMS release more detailed information on claims that were compliant with AUC, particularly what percentage included modifier MH. This commenter stated that a high percentage of claims with modifier MH would indicate that citing a 9–10 percent compliance rate in the proposed rule is disingenuous since modifier MH likely indicates that the ordering professional and furnishing professional have not established a communication process and those claims would have been denied in the payment penalty phase.

Response: We appreciate the extensive and thoughtful comments and recommendations on the AUC program and the proposal to begin the payment penalty phase of the program on the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19. We also appreciate that stakeholders would like CMS to do more to address the extensive concerns stakeholders have about the appropriateness of the AUC program. However, we note that this program is required by statute, and must implement the program within the bounds of our statutory authority. We will continue to explore opportunities for reducing burden of the AUC program by leveraging other quality programs within the provisions set forth in statute. We further appreciate the requests and suggestions for expanded education and outreach efforts. We will continue to make information available on the AUC website and explore more opportunities for increasing these efforts and the scope of information available, including reporting compliance during the remainder of the educational and operations testing period, to assist all stakeholders in better understanding and complying with the AUC program requirements.

After consideration of public comments, we are finalizing our proposal to begin the payment penalty phase of the AUC program on the later of January 1, 2023 or the January 1 that follows the declared end of the PHE for COVID–19.

5. Summary

In summary, we provided clarifications and proposals around the

scope of the AUC program specifically pertaining to updates or modifications to orders for advanced diagnostic imaging services and the extreme and uncontrollable circumstances significant hardship exception. We also proposed several claims processing solutions to ensure accurate identification of claims that are and are not subject to the AUC program requirements. These proposals addressed special circumstances related to: services furnished by a CAH, services paid under the Maryland Total Cost of Care Model, inpatients converted to outpatients, situations when Medicare is the secondary payer, and imaging services ordered prior to the payment penalty phase but furnished on or after the start of the payment penalty phase. We also discussed identifying the ordering professional on practitioner claims for the imaging service and request feedback on whether it is more appropriate to deny or return claims that fail AUC claims processing edits. We also proposed to begin the AUC claims processing systems edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the PHE for COVID–19 ends. We invited the public to submit comments on these clarifications and proposals.

We are finalizing all proposals except our proposal to repurpose modifier MH. Specifically, we are finalizing the following:

Provisions specific to orders for advanced diagnostic imaging services that are modified in accordance with chapter 15, sections 80.6.1–4 of the Medicare BPM. When the ordering professional cannot be reached to submit a new order, the AUC consultation information that accompanied the original order is to be included on the claim for the imaging service(s) ultimately furnished.

Claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting are not subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. A new HCPCS modifier will be established to identify claims for services where the ordering professional is not required to consult AUC and when previously established modifiers described above (MA–MG) do not apply. These are claims for which system edits cannot automatically exclude the claim. This new modifier will be used to identify practitioner claims for the PC of advanced diagnostic imaging services

⁹¹ <https://www.govinfo.gov/content/pkg/CRPT-117hrpt96/pdf/CRPT-117hrpt96.pdf>.

that are not subject to the AUC program because the TC was not furnished in an applicable setting and when CMS has not identified an automated mechanism to identify the claim.

We will allow institutional claims with condition code 44 to bypass AUC claims processing edits.

We will allow claims that identify Medicare as the secondary payer (using block 1 or the electronic equivalent of the practitioner claims and using FL 50/51 or the electronic equivalent of institutional claims) to bypass the AUC program claims processing edits.

For imaging services ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, the furnishing professional is to apply the new HCPCS modifier that will be created as discussed above for use on claims for advanced diagnostic imaging services that are not subject to the AUC program that are not otherwise identified by modifiers MA—MG or edits within the claims processing system.

End the use of modifier QQ when the payment penalty phase begins and use a specific modifier to identify scenarios where the ordering professional is not required to consult AUC and the claim is not required to report AUC consultation information when other modifiers do not apply and claims system edits cannot automatically exclude the claims. We will not finalize as proposed, to repurpose modifier MH for this purpose. Instead, we will establish a new HCPCS modifier and intend to end the use of modifier MH when the payment penalty phase begins.

Limit AUC program claims processing edits to apply only to institutional claim type of bill 13x (hospital outpatient) and, for professional claims, limit the edits to claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC).

Begin the payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19.

We will continue to post information on our website for this program, accessible at www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.

G. Removal of Selected National Coverage Determinations

CMS periodically identifies and removes National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current

information, in other words those items and services that no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. Clinical science and technology evolve, and items and services that were once considered state-of-the-art or cutting edge and experimental may be established as reasonable and necessary for Medicare beneficiaries or replaced by more beneficial technologies or clinical paradigms.

In the CY 2021 PFS final rule (85 FR 84472), we established rulemaking as an appropriate vehicle for receiving public comment on removing outdated NCDs, replacing the prior subregulatory administrative process used on two occasions in 2013 and 2015. Using rulemaking under section 1871(a)(2) of the Act allows us to consider removal of several NCDs at once as compared to the public comment process established in section 1862(l) of the Act, to be used in making and reconsidering individual NCDs.

Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). On the other hand, removing an NCD that bars coverage for an item or service under title XVIII of the Act (that is, national noncoverage NCD), allows MACs to cover the item or service if the MAC determines that such action is appropriate under the statute. Removing a national non-coverage NCD may permit more immediate access to technologies that may now be beneficial for some uses. As the scientific community continues to conduct research, which produces new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions.

In the CY 2021 PFS final rule, we did not establish an exclusive list of criteria that we would use for identifying and evaluating NCDs for removal. Instead, based on recommendations in public comments, and to be more flexible and nimble, we added considerations to the six factors established in 2013 to guide our decision making process. In addition to the six factors listed below, we also consider the general age of an NCD, changes in medical practice/standard of care, the pace of medical technology development since the last determination, and availability and quality of clinical evidence and information to support removal of an NCD. We would consider proposing the

removal of an NCD if any of the following factors are present:

- We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an “NCD” as defined in sections 1862(l) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the statute.

When we evaluate particular NCDs for removal, we take into account information gathered from stakeholders, the claims data for those items and services, and factors such as whether there may be documentation requirements within the NCD that are outdated and create a barrier to coverage. The rulemaking process provides an opportunity to consider public input before the NCD would be removed. We could decide to retain those NCDs after considering public comments.

In Table 33, we list the NCDs that we proposed to remove. In addition to conducting an internal review to identify appropriate NCDs for removal, we receive removal requests from a variety of external stakeholders, such as medical specialty societies, device manufacturers, beneficiaries, physicians and providers, and other interested individuals. Additionally, sometimes topics are brought to our attention by the MAC medical directors. Also, we received comments to the NCD Removal proposal in response to the CY 2021 PFS proposed rule suggesting another seven NCDs for CMS to consider removing. After reviewing those comments and considering other available evidence and information, we proposed to remove one of those seven NCDs in this rulemaking cycle. We have opened a national coverage analysis (NCA) using the NCD process for one and stated in the CY 2021 PFS proposed rule that we believed the other five NCDs should be retained.

We solicited comment on the two NCDs discussed in Table 33, as well as comments recommending other NCDs for CMS to consider for removal in a future rulemaking or through the NCD process.

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