speakers' outlines of the topics to be discussed at the public hearing by Tuesday, December 10, 2019. If no outlines are received by December 3, 2019, the public hearing will be cancelled.

ADDRESSES: The public hearing is being held in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW, Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present a valid photo identification to enter the building.

Send Submissions to CC:PA:LPD:PR (REG–104554–18 and REG–104870–18), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday to CC:PA:LPD:PR (REG–104554–18 and REG–104870–18), Couriers Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–104554–18 and REG–104870–18).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Charles Gorham, (202) 317–5091; concerning submissions of comments, the hearing and/or to be placed on the building access list to attend the hearing, Regina Johnson at (202) 317–6901 (not toll-free numbers), *fdms.database@irscounsel.treas.gov.*

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking (REG–104554–18 and REG–104870–18) that was published in the **Federal Register** on Monday, September 9, 2019 (84 FR 47175 and 47191).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing that submitted written comments by November 8, 2019, must submit an outline of the topics to be addressed and the amount of time to be devoted to each topic by Tuesday, December 3, 2019.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing or by contacting the Publications and Regulations Branch at (202) 317–6901 (not a toll-free number).

Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

Martin V. Franks,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2019–25161 Filed 11–20–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ68

Provider-Based Requirements

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations concerning collection and recovery by VA for medical care and services provided to an individual at a VA medical facility for treatment of a nonservice-connected condition. Specifically, this rulemaking would add a regulation that establishes the requirements VA will use to determine whether a VA medical facility has provider-based status. Such determination affects the amount VA can recover from a third party for the cost of the nonservice-connected care. Currently, VA uses the requirements established by the Centers for Medicare and Medicaid Services to determine whether the facility has provider-based status; however, it is necessary for VA to establish its own requirements that are tailored to VA's unique operation and structure.

DATES: Comments must be received by VA on or before January 21, 2020.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov*, by mail or hand-delivery to Director, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1064, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll-free number.) Comments should indicate that they are submitted in response to RIN 2900–AQ68, Provider-Based Requirements. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1064, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Director of Policy and Planning, Office of Community Care (10D), Ptarmigan at Cherry Creek Denver, CO, 80209, *Joseph.Duran2@va.gov* or (303) 372–4629. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: VA is authorized under 38 U.S.C. 1729 to recover or collect from a third party the reasonable charges for medical care or services VA furnishes to an individual for a non-service connected disability, to the extent that the individual, or the provider of care or services, would be eligible to receive payment from the third party if the care or services had not been furnished by VA. VA's collection or recovery under section 1729 is limited to care or services furnished by VA for a nonservice-connected disability: Incurred incident to the individual's employment and covered under a worker's compensation law or plan that provides reimbursement or indemnification for such care and services; incurred as the result of a crime of personal violence that occurred in a State, or a political subdivision of a State, in which a person injured as the result of such a crime is entitled to receive health care and services at such State's or subdivision's expense for personal injuries suffered as the result of such crime; incurred as a result of a motor vehicle accident in a State that requires automobile accident reparations (no-fault) insurance; or for which the individual is entitled to care (or the payment of expenses of care) under a health plan contract.

VA implements its authority under section 1729 through regulations at title 38 Code of Federal Regulations (CFR) 17.101 through 17.106. More specifically, the methodology that VA uses to determine the amount of its collection or recovery for is established in 38 CFR 17.101. This rulemaking would primarily seek to revise this methodology with regards to calculating the reasonable charges for care and services VA provides on an outpatient basis. Prior to explaining the proposed regulatory changes for § 17.101, we provide the following background on how VA developed its current methodology for charges for outpatient

services. Historically, if VA had a specific item of medical care or service provided on an outpatient basis, VA could charge a professional charge, an outpatient facility charge, or both. These charges were developed so as to be mutually exclusive, with the expectation that both charges could be billed for the same occasion of service.

In April 2000, the Centers for Medicare and Medicaid Services (CMS) published a final rule with comment period that, in pertinent part, codified its long-standing use of provider-based status in regulation at 42 CFR 413.65. 65 FR 18434 (April 7, 2000). In this final rule, CMS explained that, since the Medicare program started, some providers, referred to as main providers, had functioned as a single entity while owning and operating additional departments, locations, and facilities. These departments, locations, and facilities were referred to as provider-based and were treated as part of the main provider for Medicare purposes. In this regard, to the extent that overhead costs of the main provider, such as administrative and general costs, were shared by the provider-based facility, these costs were allowed to flow to the provider-based facility through the cost allocation process in the cost report. This was considered appropriate because these facilities were also operationally integrated, and the provider-based facility was sharing the overhead costs and revenue producing services controlled by the main provider. In the April 2000 final rulemaking, CMS defined the term provider-based status as 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. 42 CFR 413.65(a)(2). It also established specific requirements that must be met in order for CMS to recognize a facility as having provider-based status. CMS explained that specific criteria were necessary because the designation of provider-based status could result in additional Medicare payments for services furnished at the provider-based facility (outpatient facility charges), and could also increase the coinsurance liability of Medicare beneficiaries for those services. The final rule clarified that 42 CFR 413.65 applied to providers and facilities seeking Medicare payment. As VA does not seek Medicare payment, the requirements and criteria established in 42 CFR 413.65 applies to VA only if VA so establishes through its own regulations.

In December 2003, VA amended 38 CFR 17.101 to establish that VA would use the CMS provider-based criteria in 42 CFR 413.65 to more closely approximate industry standard charge structures and billing practices. 68 FR 70714 (December 19, 2003). That VA rulemaking further established two sets of charges for outpatient care consistent with Medicare: One for use by facilities that had provider-based status and one for facilities that did not have provider-based status. The facilities that had provider-based status could bill both an outpatient professional and facility charge. The facilities that did not have provider-based status could only bill a professional charge. In consideration of the fact that facilities that did not have provider-based status could only bill a professional charge, the professional charge for those facilities would be higher than the professional charge for facilities that had provider-based status, based on Medicare's higher non-facility practice expense relative value units (RVUs).

Currently, VA defines the terms provider-based and non-provider-based in 38 CFR 17.101(a)(5). Section 17.101(a)(5) defines provider-based as the outpatient department of a VA hospital or any other VA health care entity that meets CMS provider-based criteria. Provider-based entities are entitled to bill outpatient facility charges. Under § 17.101(a)(5), non-provider-based is defined as a VA health care entity (such as a small VA community-based outpatient clinic) that functions as the equivalent of a doctor's office or for other reasons does not meet CMS provider-based criteria, and, therefore, is not entitled to bill outpatient facility charges. VA establishes the use of the CMS provider-based criteria in its third-party billing through § 17.101(a)(6), which states in pertinent part that each VA health care entity are designated as either provider-based or non-provider based provider-based entities are entitled to bill outpatient facility charges; non-provider-based entities are not.

For the reasons below, VA proposes to revise 38 CFR 17.101 to remove the current regulatory requirement that VA use the CMS provider-based criteria with regards to VA billing of third parties, and proposes to add a new regulation at 38 CFR 17.100 that would establish the criteria that VA would use instead to determine whether a VA facility has provider-based status. In so doing, VA would model new proposed 38 CFR 17.100 on a majority of the current CMS provider-based criteria in 42 CFR 413.65, but VA's revisions would address the unique structure of VA's health care system, versus the CMS requirements that are more generally applicable to private health care systems. Significantly, VA is an integrated, national health care system and, therefore, some of the CMS requirements in 42 CFR 413.65, especially as they pertain to proximity limitations and licensure, are not appropriate to use for VA facilities. Those CMS requirements that are not appropriate to use for VA facilities are further identified and explained in more detail in the discussions below.

Additionally, to provide a scope for the proposed changes further explained below, we note that as of June 2018, 93 percent out of the total number of VA's facilities from which recoverable costs for care or services are provided (VA's billable facilities) already meet the current CMS provider-based criteria under 42 CFR 413.65(d) and (e) to permit VA to bill both an outpatient professional charge and an outpatient facility charge. Therefore, the proposed changes explained below would only have a potential effect in practical billing practices (to allow for the billing of an outpatient facility charge, in addition to the current billing of an outpatient professional charge) for seven percent of VA's billable facilities. More detail is provided in the section of this rulemaking that discusses the Regulatory Flexibility Act.

§ 17.100 Requirements for Provider-Based Status

We propose to add a new regulation at 38 CFR 17.100. Section 17.100 would be located under the undesignated center heading Charges, Waivers, and Collections and would be titled Requirements for provider-based status.

In proposed § 17.100(a), we would describe a clear scope for establishing this section, which is to provide the criteria we would use to determine whether a VA medical facility has provider-based status for purposes of billing for nonservice-connected and non-special treatment authority conditions. We would also explain that while these requirements are modeled after the requirements established in the CMS regulation, 42 CFR 413.65, there are some differences that are designed to address the unique operational activities of the VA health care system.

Proposed § 17.100(b) would contain the definitions that would apply to this section. While some of these terms are based on those definitions in the CMS regulation, most are defined in the context of VA's unique structure and organization as indicated within the discussions of each proposed definition below. This ensures that we use the definitions and terminology that are

most appropriate and applicable to VA's health care system.

Community Based Outpatient Clinic (CBOC) would be defined as a VA-operated, VA-funded, or VA-reimbursed site of care that is not located within a VA Medical Center. We would further explain that a CBOC can provide primary, specialty, subspecialty, mental health, or any combination of health care delivery services that can be appropriately provided in an outpatient setting. A CBOC is unique to VA, and would be consistent with other VA definitions or uses of the term.

Community Living Center (CLC) would be defined as a component of the spectrum of long-term care that provides a skilled nursing environment and houses a variety of specialty programs, such as respite care, dementia care, and skilled nursing care, for persons needing short and long stay services. We would further explain that CLCs are typically located on or near a VA medical facility and are VA-owned and operated, but may be free-standing in the community. This definition of CLC would be consistent with other VA definitions or uses of the term.

Facility would be defined as a point of care where individuals can seek health care services, to include a VA Medical Center, CBOC, Health Care Center, CLC, and Other Outpatient Services site. This definition would specifically reference the facilities within VA that currently provide health care services.

Health Care Center (HCC) would be defined as a VA-owned, VA-leased, VA-contracted, or shared clinic that is operational at least five days per week and provides primary care, mental health care, on site specialty services, and performs ambulatory surgery and/or invasive procedures that may require moderate sedation or general anesthesia. This definition would be consistent with other VA definitions or uses of the term, and is defined to reflect VA's organization and structure.

Main Provider (or parent facility/hospital or PBH) would be defined as a provider that either creates, or acquires ownership of, another facility to deliver additional health care services under its name, ownership, and financial and administrative control. This is consistent with the CMS definition of main provider in 42 CFR 413.65(a)(2). We note that VA generally refers to its main providers as provider-based hospitals (PBHs). Although these facilities operate as main providers operate in the private sector and are not subordinate facilities that would seek provider-based status, VA has historically referred to them as PBHs. For clarity, we will refer to these facilities as main providers in the preamble and regulation text. We would further explain that VAMCs and HCCs can be main providers. This definition would reflect VA's organization and structure, and reference those facilities within VA that are examples of main providers.

Other Outpatient Services (OOS) would be defined as a site that provides outpatient services to veterans, but does not meet the definition of a CBOC or HCC. This definition would be consistent with other VA definitions or uses of the term, as well as VA's structure and organization. Examples of OOS can include sleep centers, post-traumatic stress disorder clinics, and a clinic without primary care or mental health services.

Prospective Payment System (PPS) would be defined as a method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (for example, Medicare Severity Diagnosis-Related Groups for inpatient hospital services furnished by most acute care hospitals). This definition would be consistent with the definition used by CMS.

Provider-Based Outpatient Facility (PBO) would be defined as a provider of health care services that is either created by, or acquired by, a main provider for the purpose of furnishing additional health care services under the ownership, administrative, and financial control of the main provider and meets the criteria outlined in this section. CMS does not define the general term of provider-based outpatient facility and instead, CMS separately defines the types of facilities or entities that could obtain provider-based status, to include department of a provider, provider-based entity, and remote location of a hospital. However, for the purposes of VA, it is not necessary to distinguish between the different types of facilities, and therefore, VA will have one term to broadly encompass all provider-based outpatient facilities.

Remote Location of a Hospital would be a CBOC, OOS site, or HCC that is located offsite from the main facility. This definition would differ from the definition provided in 42 CFR 413.65 in order to specifically define this term within the context of VA's facilities and reflect VA's unique organization and structure.

VA Medical Center (VAMC) would be defined as a VA facility that provides at least two categories of care (inpatient, outpatient, residential, or institutional extended care). This definition would be consistent with other VA definitions or uses of the term, as well as VA's structure and organization.

In proposed § 17.100(c), we would set forth the criteria that would be used to determine whether a facility has provider-based status for purposes of billing for nonservice-connected and non-special treatment authority conditions. Section 17.100(c) is largely modeled after the requirements for all facilities or organizations in 42 CFR 413.65(d), additional requirements applicable to off-campus facilities or organizations in 42 CFR 413.65(e), and obligations of hospital outpatient departments and hospital-based entities in 42 CFR 413.65(g).

In proposed § 17.100(c)(1), we would require that the facility seeking provider-based status and the main provider operate under the same license. This requirement would be consistent with the CMS provider-based criteria located at 42 CFR 413.65(d)(1), which generally requires a department of a provider, the remote location of a hospital, or the satellite facility and the main provider operate under the same license. As previously explained, VA is not distinguishing between departments of providers, remote locations of a hospital, satellite facilities, and other provider-based facilities. Therefore, proposed paragraph (c)(1) would state that the facility seeking provider-based status and the main provider operate under the same license. Because VA is a Federal entity, VA facilities are not licensed, and are not required to be licensed, under any State laws or other State authorities. Therefore, we would also explain that VA facilities are not licensed by States but are considered licensed by VA for the purpose of collection and recovery as part of VA's national organization structure and in accordance with VA standards, including those recognized by VA's Office of the Medical Inspector and Inspector General, as well as standards of major healthcare accreditation organizations such as The Joint Commission as applicable to specific VA facilities.

In proposed § 17.100(c)(2), we would require that the clinical services of the facility seeking provider-based status and the main provider be integrated. We would further explain that integration is demonstrated by several factors, which would be listed in the regulation. These factors would include (1) the professional staff at the facility seeking provider-based status has clinical privileges at the main provider; (2) the main provider maintains the same

monitoring and oversight (*i.e.* credentialing and privileging) of the facility seeking provider-based status as it does for any other department of the provider; (3) the medical director of the facility 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; (4) the medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility seeking provider-based status, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility seeking provider-based status and the main provider; (5) the medical records for patients treated in the facility are integrated into a unified retrieval system (or cross reference) of the main provider; (6) inpatient and outpatient services of the facility seeking provider-based status and the main provider are integrated, and patients treated at the facility 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; and (7) inpatient and outpatient services of the facility seeking provider-based status and the main provider are recognized under the main provider's accreditation. The first six factors would be consistent with the CMS criteria located at 42 CFR 413.65(d)(2). However, the seventh factor, regarding accreditation, would be additional factor that demonstrates integration for VA facilities. This would reflect the unique structure and organization of VA, in which inpatient and outpatient services of VA facilities are recognized under the main provider's accreditation.

In proposed § 17.100(c)(3), we would propose to require financial integration of the facility seeking provider-based status and the main provider. Specifically, we would require that the financial operations of the facility seeking provider-based status 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. We would also require that the costs of a facility that is a hospital department be reported in a cost center of the provider, costs of a provider-based facility other than a hospital department be reported in the appropriate cost center or cost centers of the main provider. This would be consistent with CMS requirements in 42 CFR 413.65(d)(3). However, we would also require that the main provider's integrated health care system manpower and labor budget and the financial status of any provider-based facility be incorporated and readily identified in the main provider's integrated system reports. This additional requirement would reflect that the main provider has administrative and financial control of the provider-based facility, and would be consistent with similar CMS requirements in 42 CFR 413.65(d)(3). This would reflect VA's current structure and organization in which a main provider has such control, particularly budgetary, over facilities.

Under proposed § 17.100(c)(4), we would include a requirement for public awareness. Specifically, we would require that the facility seeking provider-based status be held out to the public (and other payers) as part of the main provider. This would be exhibited by the patients of the facility being made aware that the facility is part of a main provider and that they will be billed accordingly. This would be consistent with the CMS requirement for public awareness in 42 CFR 413.65(d)(4). In addition, we would also propose that all literature, brochures, and public relations newsletters from the facility seeking provider-based status include the relationship between the main provider and the facility. This is current VA practice for facilities associated or affiliated with a main provider and reflects the relationship between the facilities.

Proposed § 17.100(c)(5) would contain obligations when the facility seeking provider-based status is a hospital outpatient department or hospital-based entity, including (1) compliance with the ''antidumping'' rules of 42 CFR 489.20(l), (m), (q), and (r) and 42 CFR 489.24; (2) physician services must be billed with the correct site-of-service so that appropriate physician and practitioner amounts can be determined; (3) physicians are obligated to comply with the non-discrimination provisions in 42 CFR 489.10; (4) the facility seeking provider-based status must treat all Medicare patients seen on an urgent/emergent basis as hospital outpatients; (5) in the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based facility, payments for services in the hospital outpatient department of hospital-based facility are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at 42 CFR 412.2(c)(5) and at 42 CFR 413.40(c)(2), respectively; (6) the hospital outpatient department must meet applicable VA policy pertaining to hospital health and safety programs; and (7) VA must treat any facility that is located on the main hospital campus as a department of the hospital. The criteria described in (1)–(7) are largely consistent with CMS regulations at § 413.65(d)(5) and (g).

We note that we would not propose to include all of the criteria located at § 413.65(g), Obligations of hospital outpatient departments and hospital-based entities, because some of the requirements are not applicable to VA. For example, § 413.65(g)(3) (hospital outpatient departments must comply with all the terms of the hospital's provider agreement) and § 413.65(g)(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, certain requirements must be met) are not included because they are not applicable.

In proposed § 17.100(c)(6), we would include the requirement that the facility seeking provider-based status is operated under the control of the main provider. Such control would require (1) the main provider and the facility seeking provider-based status have the same governing body; (2) the facility seeking provider-based status is operated under the same organizational documents as the main provider (*e.g.* the facility is subject to common bylaws and operating decisions of the main provider's governing body); (3) 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 code of conduct), and final approval for medical staff appointments in the facility seeking provider-based status. This is modeled after the criteria in § 413.65(e)(1) which requires operation under the ownership and control of the main provider as an additional requirement applicable to off-campus facilities or organizations. However, we propose to remove the

ownership requirements because, in the VA structure, main providers do not own other facilities.

Proposed § 17.100(c)(7) would establish the requirement for administration and supervision of the facility seeking provider-based status. Significantly, the reporting relationship between the facility 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 further identified requirements. These include (1) the facility seeking provider-based status must be under the direct supervision of the main provider, (2) the facility seeking provider-based status must be operated under the same monitoring and oversight by the main 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; and (3) administrative functions (*i.e.* billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services) of the facility seeking provider-based status are integrated with those of the main provider.

We would further explain that as part of the requirement for the same monitoring and oversight located in proposed § 17.100(c)(7)(ii), the facility director or individual responsibility for daily operations at the facility must maintain 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 is accountable to the governing body of the main provider, in the same manner as any department head of the provider. In addition, we would explain that the requirement of integrated administrative functions, as set forth in proposed § 17.100(c)(7)(iii), includes that either the same employees or group of employees handle the identified administrative functions for the facility and main provider, or those functions are contracted out under the same contract agreement; or are handled under different contract agreements, with the contract of the facility or organization being managed by the main provider. The criteria under proposed § 17.100(c)(7) are consistent with those under the CMS regulations at 42 CFR 413.65(e)(2).

Lastly, under proposed § 17.100(d), we would illustrate how the criteria are applied when VA does not own the facility, but operates under a contract, and in the situation when the employees at a VA facility are contract employees. We would explain that, (1) a VA facility that is seeking provider-based status that exists under contract arrangements, where only VA patients are seen, may be designated as provider-based as long as the provider-based requirements in this section are met; (2) A VA facility seeking provider-based status that exists under contract arrangements, where VA patients and non-VA patients are seen at the same non-VA owned facility, will have the same provider-based status as the non-VA owned facility that is hosting the VA facility; and (3) a VA owned and operated facility seeking provider-based status, where some or all of the staff are contracted employees, may be designated as provider-based as long as the provider-based requirements in this section are met. This is because the facility is still considered VA owned and operated, regardless of whether the staff is contracted or not.

The CMS requirements include numerous other provisions that are applicable to private health care systems, but are not applicable to the VA health care system. For example, in the proposed rulemaking we are not including the information in 42 CFR 413.65(b) or (c) on what is required to seek a determination of provider-based status from CMS and what is required for reporting material changes in relationships to CMS, because VA and not CMS will make the determination of whether a VA facility has provider-based status.

In addition, this proposed rulemaking does not include the CMS criteria at 42 CFR 413.65(e)(3) regarding location requirements. These include, generally, that the facility is located within a 35 mile radius of the campus of the potential main provider or that the facility is owned and operated by a hospital that has a disproportionate share adjustment greater than 11.75 percent and that the facility demonstrates a high level of integration with the main provider by showing that it serves the same patient population as the main provider. Although in the private sector, mileage between the main provider and the facility seeking provider-based status demonstrates a level of integration, we believe that the same is not true for VA.

VA is a nationwide health care system that is structured to require all facilities that are not main providers be controlled by and financially and administratively integrated with the main provider in its region, regardless of mileage. In this regard, each designated region has one main provider and when VA acquires or creates a new facility (that is not a main provider), the new facility is automatically paired with the main provider that is in its region. The new facility is assigned a shared station number with the main provider that has a unique suffix and is under the main provider's control. We emphasize that the pairing is only based on location to the extent that the new facility is within the main provider's region; it does not depend upon a certain mileage requirement. For example, in the State of Maine, there is one main provider and all other facilities, regardless of distance from the main provider, are administratively and financially integrated with and controlled by the main provider. It does not matter whether the facility is 20 miles away or 200 miles away. Therefore, VA believes that the location requirement is not a relevant criterion to determine integration within the VA system.

Moreover, the proposed rulemaking does not include the requirements for joint ventures under 42 CFR 413.65(f), management contracts under 42 CFR 413.65(h), inappropriate treatment of a facility or organization as provider-based under 42 CFR 413.65(j), temporary treatment as provider-based under 42 CFR 413.65(k), correction of errors under 42 CFR 413.65(l), the status of Indian Health Service and Tribal facilities and organizations under 42 CFR 413.65(m), FQHCs and look alikes under 42 CFR 413.65(n), and effective date of provider-based status under 42 CFR 413.65(o). VA believes that these provisions are not pertinent to VA's structure as a national health care system for veterans, and therefore, we will not include these or similarly not relevant provisions into the proposed rulemaking.

§ 17.101 Collection or Recovery by VA for Medical Care or Services Provided or Furnished to a Veteran for a Nonservice-Connected Disability

We propose to revise § 17.101(a)(5) by removing the definitions of provider-based and non-provider-based. The term provider-based outpatient facility will be defined in § 17.100(b)(2). Therefore, we do not believe that it needs to be defined in § 17.101. We also propose to remove the definition of non-provider-based. CMS does not define that term in § 413.65 and we do not believe it is necessary to define. If a facility does not meet the criteria in § 17.100, the facility will simply not have provider-based status.

We propose to amend § 17.101(a) by first stating that the paragraph will cover charges related to provider-based

status. We would explain that facilities that have provider-based status by meet the criteria in § 17.100 would be entitled to bill outpatient facility charges and professional charges. The professional charges for these facilities would be produced by the methodologies set forth in this section based on facility expense RVUs. Facilities that do not have provider-based status because it did not meet the criteria in § 17.100 would not be permitted to bill outpatient facility charges and could only bill a professional charge. The professional charges for these facilities would be produced by the methodologies set forth in this section based on non-facility practice expense RVUs.

§ 17.106 VA Collection Rules; Third-Party Payers

As previously discussed, under 38 U.S.C. 1729, VA has the right to recover or collect reasonable charges for medical care or services from a third party under four circumstances. In addition, section 1729(f) provides that no law of any State or of any political subdivision of a State, and no provision of any contract or other agreement, shall operate to prevent recovery or collection by the United States under this section or with respect to care or services furnished under section 1784 of this title. VA has established rules for third party payers in 38 CFR 17.106. Specifically, § 17.106(f) contains the general rules for the administration of section 1729 and this part, with clarifying examples of when a third-party may not reduce, offset, or request a refund for payments made to VA. Section 17.106(f)(2) explicitly provides that the list of examples is not exclusive. We propose to add another example to 38 CFR 17.106(f)(2) to clarify that third parties cannot reduce or refuse payment based on VA's designation that a facility is provider-based.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

This rule contains no collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small facilities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Over 90 per cent of VA's current billing facilities presently engage in the practices that would be enabled by this rule for a remaining small percentage of VA facilities. Additionally, while the rule would allow for recognition of an additional set of billable charges for the small percentage of VA facilities that to not already engage in such practices, the rule would not guarantee such charges would be paid by third parties or collected by VA. The estimated average annual potential impact of less than $4 million would otherwise not be significant when considered to apply to the aggregate of typical third-party insurers or payers in the U.S. health care industry at large. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Office of Management and Budget has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and determined that it is a significant regulatory action under Executive Order 12866, because it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm* by following the link for VA Regulations Published from FY 2004 through FYTD.

This proposed rule is not subject to the requirements of E.O. 13771 because this proposed rule results in no more than *de minimis* costs.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule is not likely to have such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.008—Veterans Domiciliary Care; 64.011—Veterans Dental Care; 64.012—Veterans Prescription Service; 64.013—Veterans Prosthetic Appliances; 64.014—Veterans State Domiciliary Care; 64.015—Veterans State Nursing Home Care; 64.026—Veterans State Adult Day Health Care; 64.039—CHAMPVA; 64.040—VHA Inpatient Medicine; 64.041—VHA Outpatient Specialty Care; 64.042—VHA Inpatient Surgery; 64.043—VHA Mental Health Residential; 64.044—VHA Home Care; 64.045—VHA Outpatient Ancillary Services; 64.046—VHA Inpatient Psychiatry; 64.047—VHA Primary Care; 64.048—VHA Mental Health clinics; 64.049—VHA Community Living Center; 64.050—VHA Diagnostic Care.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Health care, Health facilities, Health professions, Health records, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this

document on May 3, 2019, for publication.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 17 as set forth below:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

■ 2. Add § 17.100 under the undesignated center heading ''Charges, Waivers, and Collections'' to read as follows:

§ 17.100 Requirements for provider-based status.

(a) *Scope.* This section establishes the criteria that VA uses to determine whether a VA medical facility is designated as provider-based for purposes of billing for non-service-connected and non-special treatment authority conditions.

(b) *Definitions.* For purposes of this section:

Community Based Outpatient Clinic (CBOC). A CBOC is a VA-operated, VA-funded, or VA-reimbursed site of care that is not located within a VA Medical Center. A CBOC can provide primary, specialty, subspecialty, mental health, or any combination of health care delivery services that can be appropriately provided in an outpatient setting.

Community Living Center (CLC). A CLC is a component of the spectrum of long-term care that provides a skilled nursing environment and houses a variety of specialty programs for persons needing short and long stay services. VA CLCs are typically located on, or near a VA medical facility and are VA-owned and operated, but may be free-standing in the community.

Facility. A facility is a point of care where individuals can seek VA health care services, to include a VA Medical Center, CBOC, Health Care Center, CLC, and Other Outpatient Services site.

Health Care Center (HCC). An HCC is a VA-owned, VA-leased, VA-contracted or shared clinic that is operational at least five days per week and provides primary care, mental health care, on site specialty services, and performs ambulatory surgery and/or invasive procedures that may require moderate sedation or general anesthesia.

Main provider. A main provider (or parent facility/hospital or provider-based hospital (PBH)) is a provider that either creates, or acquires ownership of, another facility to deliver additional health care services under its name, ownership, and financial and administrative control. For example, VA Medical Centers and HCCs can be main providers.

Other Outpatient Services (OOS). A site that provides outpatient services to veterans, but does not meet the definition of a CBOC or HCC per this section.

Prospective Payment System (PPS). A Prospective Payment System (PPS) is a method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (for example, Medicare Severity Diagnosis-Related Groups for inpatient hospital services furnished by most acute care hospitals).

Provider-based outpatient facility (PBO). A provider-based outpatient facility is a provider of health care services that is either created by, or acquired by, a main provider for the purpose of furnishing additional health care services under the ownership, administrative, and financial control of the main provider, and meets the criteria outlined in this section.

Remote location of a hospital. A remote location of a hospital is a CBOC, OOS Site, or HCC that is located offsite from the main facility.

VA Medical Center (VAMC). A VAMC is a VA facility that provides at least two categories of care (inpatient, outpatient, residential, or institutional extended care).

(c) *Criteria for provider-based status.* In order to be designated as a provider-based facility, the following criteria must be met:

(1) *Licensure.* The facility seeking provider-based status and the main provider must operate under the same license. VA facilities are not licensed by States but all VA facilities are considered licensed for the purpose of collection and recovery by VA as part of VA's national organization structure and in accordance with VA standards, including standards established or recognized by VA's Offices of the Medical Inspector and Inspector General and major healthcare accreditation organizations.

(2) *Clinical services.* The clinical services of the facility seeking provider-based status and the main provider must be integrated. Integration is demonstrated by the following:

(i) The professional staff of the facility has clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight (*i.e.* credentialing and privileging) of the facility seeking provider-based status as it does for any other department of the provider.

(iii) The medical director of the facility 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) The medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility seeking provider-based status, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility seeking provider-based status are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility seeking provider-based status and the main provider are integrated, and patients treated at the facility 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.

(vii) Inpatient and outpatient services of the facility seeking provider-based status and the main provider are recognized under the main provider's accreditation.

(3) *Financial integration.* The financial operations of the facility seeking provider-based status 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. The costs of a facility that is a hospital department are reported in a cost center of the provider, costs of a facility other than a hospital department are reported in the appropriate cost center or cost centers of the main provider. The main provider's integrated health care system manpower and labor budget and the

financial status of any facility seeking provider-based status is incorporated and readily identified in the main provider's integrated system reports.

(4) *Public awareness.* The facility seeking provider-based status must be held out to the public (and other payers) as part of the main provider. Patients of the facility must be made aware that the facility is part of a main provider and that they will be billed accordingly. All literature, brochures, and public relations newsletters from the facility seeking provider-based status must provide the relationship between the main provider and the facility.

(5) *Obligations of hospital outpatient departments and hospital-based facilities.* If the facility seeking provider-based status is a hospital outpatient department or hospital-based facility, the facility must fulfill the obligations described in this paragraph:

(i) The hospital outpatient department must comply with the antidumping rules of 42 CFR 489.20(l), (m), (q), and (r) and § 489.24.

(ii) Physician services furnished in hospital outpatient departments or hospital-based facilities must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined based on their geographical location.

(iii) Physicians who work in hospital outpatient departments or hospital-based facilities are obligated to comply with the non-discrimination provisions in 42 CFR 489.10(b).

(iv) Hospital outpatient departments must treat all Medicare patients seen on an urgent/emergent basis as hospital outpatients.

(v) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based facility, payments for services in the hospital outpatient department or hospital-based facility are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at 42 CFR 412.2(c)(5) and at 42 CFR 413.40(c)(2), respectively.

(vi) The hospital outpatient department must meet applicable VA policies pertaining to hospital health and safety programs.

(vii) VA must treat any facility that is located on the main hospital campus as a department of the hospital.

(6) *Operation under the control of the main provider.* The facility seeking provider-based status is operated under the control of the main provider. Control of the main provider requires:

(i) The main provider and the facility seeking provider-based status have the same governing body.

(ii) The facility seeking provider-based status is operated under the same organizational documents as the main provider. For example, the facility seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider.

(iii) 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 code of conduct), and final approval for medical staff appointments in the facility seeking provider-based status.

(7) *Administration and Supervision.* The reporting relationship between the facility 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 seeking provider-based status is under the direct supervision of the main provider.

(ii) The facility seeking provider-based status is operated under the same monitoring and oversight by the main 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 director or individual responsible for daily operations at the facility:

(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 seeking provider-based status are integrated with those of the main provider where the facility 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 and the main provider, or the administrative functions for both the facility and the main provider are contracted out under the same contract agreement; or are handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(d) *Illustrations of how the criteria are applied.* (1) A VA facility that is seeking provider-based status that exists under contract arrangements, where only VA patients are seen, may be designated as provider-based if the provider-based requirements in this section are met.

(2) A VA facility seeking provider-based status that exists under contract arrangements, where VA patients and non-VA patients are seen at the same non-VA owned facility, will have the same provider-based status as the non-VA owned facility that is hosting the VA facility.

(3) A VA owned and operated facility seeking provider-based status, where some or all of the staff are contracted employees, may be designated as provider-based if the provider-based requirements in this section are met.

■ 2. Amend § 17.101 by:

■ a. Revising the section heading;

■ b. Removing the definitions ''Non-provider-based'' and ''Provider-based'' from paragraph (a)(5); and

■ c. Revising paragraph (a)(6).

The revisions read as follows:

§ 17.101 Collection or recovery by VA for medical care or services provided or furnished to a veteran for a non-service connected disability.

(a) * * *

(6) *Provider-based status and charges.* Facilities that have provider-based status by meeting the criteria in § 17.100 are entitled to bill outpatient facility charges and professional charges. The professional charges for these facilities are produced by the methodologies set forth in this section based on facility expense RVUs. Facilities that do not have provider-based status because they do not meet the criteria in § 17.100 are not permitted to bill outpatient facility charges and can only bill a professional charge. The professional charges for these facilities are produced by the methodologies set forth in this section based on non-facility practice expense RVUs.

* * * * *

■ 3. Amend § 17.106 by adding paragraph (f)(2)(viii) to read as follows:

§ 17.106 VA collection rules; third-party payers.

* * * * *

(f) * * *

(2) * * *

(viii) A third party may not reduce or refuse payment if the facility where the medical treatment was furnished is designated by VA as provider-based, but

the facility does not meet the provider-based status requirements under 42 CFR 413.65 Centers.

* * * * *

[FR Doc. 2019–24880 Filed 11–20–19; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2019–0553; FRL–10002–39–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; 2019 Amendments to West Virginia's Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of West Virginia. This revision updates the effective date of the national ambient air quality standards (NAAQS) and the associated monitoring reference and equivalent methods for those NAAQS that West Virginia incorporates by reference into its state regulations. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before December 23, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2019–0553, at *https://www.regulations.gov,* or via email to *spielberger.susan@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Joseph Schulingkamp, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2021. Mr. Schulingkamp can also be reached via electronic mail at *schulingkamp.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 6, 2019, the West Virginia Department of Environmental Protection (WVDEP) submitted a formal revision to its SIP pertaining to amendments of Legislative Rule, 45CSR8—Ambient Air Quality Standards. The SIP submittal updates the version of the federal NAAQS and the associated monitoring reference and equivalent methods for those NAAQS that West Virginia incorporates by reference into West Virginia's legislative rules.

I. Summary of SIP Revision

WVDEP has historically chosen to incorporate by reference the federal NAAQS, found at 40 CFR part 50, and the associated federal ambient air monitoring reference methods and equivalent methods for these NAAQS found at 40 CFR part 53. When incorporating by reference these federal regulations, WVDEP has specified that it is incorporating by reference these regulations as they existed on a certain date. The incorporation by reference of the NAAQS that is currently SIP-approved by EPA incorporates by reference 40 CFR parts 50 and 53 as they existed on June 1, 2017. This SIP revision updates the State's incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods, found in 40 CFR parts 50 and 53, respectively. Since the last West Virginia incorporation by reference of June 1, 2017, EPA reviewed the primary standards for oxides of nitrogen (NO_X), as required by CAA section 109(d), and retained the current 1-hour and annual nitrogen dioxide (NO_2) standards without revision. *See* 83 FR 17226. EPA has not made any changes to the ambient air monitoring reference methods or any ambient air monitoring equivalent methods since the last effective date of the West Virginia rule.

The amendments to the legislative rule include the following changes: To section 45–8–1 (General), the filing, effective, and incorporation by reference dates are changed to reflect the update of the legislative rule, subsection 1.5 was renumbered to subsection 1.6, and a new subsection 1.5 (Sunset Provision) was added; to section 45–8–3 (Adoption of Standards), the dates of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods that are to be incorporated by reference are changed. The filing and effective dates of the legislative rule were updated to April 24, 2019 and June 1, 2019 respectively. The date of the federal rules in 40 CFR parts 50 and 53 that are being incorporated by reference into 45–8–3 are changed from June 1, 2017 to June 1, 2018.

II. Proposed Action

EPA is proposing to approve the West Virginia SIP revision updating the date of incorporation by reference, which was submitted on May 6, 2019. EPA is soliciting public comments on the update to West Virginia's incorporation by reference. Please note that EPA is not seeking public comment on the level of the NAAQS being incorporated by reference into the West Virginia regulations. An opportunity for public comment on the level of each individual NAAQS was given when EPA proposed each such NAAQS. Relevant comments will be considered before taking final action.

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference 45CSR8, as effective on June 1, 2019. EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting