

under § 89.5, before publishing the final significant guidance document.

(e) For each significant guidance document where the agency and the Administrator of OIRA agree that exigency, safety, health, or other compelling cause warrants an exemption from some or all requirements under paragraph (b) of this section, the agency must incorporate that finding and a brief statement of reasons for the finding into the guidance.

(f) For all significant guidance exempt from requirements under this section as permitted by paragraph (b) of this section, such significant guidance shall be treated as temporary and will be rescinded by operation of law 270 days after it is published. The agency may make the temporary significant guidance permanent before the automatic rescission by following the procedures outlined for all significant guidance not exempt under paragraph (b).

(g) This section does not apply to pre-enforcement rulings, defined in § 89.2(g), that are guidance under this rule.

§ 89.7 Petitions for withdrawal or modification.

(a) Any member of the public may petition an agency for withdrawal or modification of a guidance document issued by the agency.

(b) Such a petition must be submitted in writing; include an email address and mailing address, as well as any other preferred means for the agency to respond electronically to the petitioner (where the petitioner has a means of electronic communication); identify the guidance document that is the subject of the petition; and state in detail the reason(s) for requesting withdrawal or modification.

(c) A petition must be directed to the relevant agency official, pursuant to instructions provided on the website described in § 89.5.

(d) The agency may choose to withdraw, modify, or retain a guidance document.

(e) Under this section an agency must provide a response in writing to a petition that meets the requirements of paragraph (b) of this section promptly, but no later than 90 days after receiving the petition.

§ 89.8 Enforceability.

This rule is intended to improve the internal management of the Department. As such, it is for the use of Department personnel only and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at

law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Signed at Washington, DC, this 19th day of August, 2020.

Jonathan A. Wolfson,
Deputy Assistant Secretary of Labor for Policy.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ68

Provider-Based Requirements

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final, with no changes, a proposed rule to revise its medical 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 adds a regulation that establishes the requirements VA will use to determine whether a VA medical facility has provider-based status.

DATES: This final rule is effective on September 28, 2020.

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Office of Community Care (10D), Veterans Health Administration, Department of Veterans Affairs, Ptarmigan at Cherry Creek, Denver, CO 80209; (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.

On November 21, 2019, VA published a proposed rule to revise the methodology in § 17.101 with regards to calculating the reasonable charges for care and services VA provides on an outpatient basis. 84 FR 64235. That proposed rule primarily sought to revise 38 CFR 17.101 to remove the regulatory requirement that VA use the Centers for Medicare and Medicaid Services (CMS) provider-based criteria with regards to VA billing of third parties, and sought to add a new regulation at 38 CFR 17.100 to establish the criteria that VA would use instead to determine whether a VA facility has provider-based status. In so doing, VA modelled a majority of the criteria in new proposed 38 CFR 17.100 on CMS provider-based criteria in 42 CFR 413.65, but VA's revisions addressed the unique structure of VA's health care system, versus the CMS requirements that are more generally applicable to private health care systems. We reiterate from the proposed rule that 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. 84 FR 64235, 64236. The CMS requirements that were not appropriate to use for VA facilities were further identified and explained in more detail in the proposed rule, as were the alternative VA criteria in § 17.100 as proposed. 84 FR 64235, 64236–64239.

VA received three comments in response to the proposed rule, all of which supported the proposed rule and none of which suggested changes to any provisions in the proposed rule. We therefore adopt the proposed rule as final with no changes.

Paperwork Reduction Act

This final 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 final rule will 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. We identified that 400 out of 745 third-party payers would qualify as small entities pursuant to the revenue threshold established by NAICS code 524114 (Direct Health and Medical Insurance Carriers) to be affected by changes in this rule. The number of 400 was derived by assuming potential effects on all entities that fell below the applicable revenue threshold, without further numeric breakout. Although this 400 number is greater than three percent of the 745 total entities, the changes in this rule do not impose any new requirements that create a significant economic impact. The changes made in § 17.100 related to revising the scope and purpose, and related to revising, adding, or removing definitions, are technical in nature and conform to existing statutory authorities and existing practices in the program. The changes in § 17.101 will allow an additional 104 VA facilities to recognize an additional billable charge under the designation of a provider-based facility, with an estimated increased revenue for VA of \$3,666,218 in FY21. This \$3,666,218 annual revenue increase divided by the 745 firms under NAICS code 524114 will result in \$4,921 additional annual costs per firm. This \$4,921 additional cost per firm divided by the total receipts per firm of \$1, 109,867,678 does not create a significant economic impact. Additional training will not be required for the 400 small entities potentially to be effected, as 97 percent of VA facilities already engage in the provider-based practices subject to the changes in § 17.101, which makes these practices well known to all potentially affected entities.

Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

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 Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

VA's regulatory 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 final rule is not subject to the requirements of E.O. 13771 because this final 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 final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 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. Brooks D. Tucker, Acting Chief of Staff, Department of Veterans Affairs, approved this document on July 22, 2020, 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 amends 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. In paragraph (a)(5), removing the definitions "Non-provider-based" and "Provider-based" from; and
■ 3. 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.

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■ 4. 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.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[EPA-R09-RCRA-2018-0568; FRL-10011-63-Region 9]

Final Determination To Approve Site Specific Flexibility for the Cocopah Landfill

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is making a final determination to approve two Site Specific Flexibility Requests (SSFRs) from Cocopah Landfill, Inc. (CLI), a subsidiary of Republic Services, Inc. (Republic), to close and monitor the Cocopah Landfill. The Cocopah Landfill is located within Indian Country on the Cocopah Indian Reservation near Somerton, Arizona and was operated by Republic and its predecessors from the 1960's to the present. EPA is promulgating a site-specific rule proposed on May 6, 2020, that approves an alternative final cover and an alternative location for the storage of facility records.

DATES: This final rule is effective on August 28, 2020.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-R09-RCRA-2018-0568 at http://www.regulations.gov. Publicly