

food, or does one evaluate the process done to the formulated finished food product (or both)?

- The current policy regarding use of the term “natural” hinges in part on the presence or absence of synthetic ingredients. For example, under the current policy synthetic forms of Vitamin D would not be used in a food claiming to be “natural,” whereas naturally sourced Vitamin D (e.g., from salmon or egg yolks) could be. Should the manner in which an ingredient is produced or sourced affect whether a food containing that ingredient may be labeled as “natural?” Please explain your reasoning.

- What can be done to ensure that consumers have a consistent and accurate understanding of the term “natural” in food labeling to ensure that it is not misleading?

- What are the public health benefits, if any, of defining the term “natural” in food labeling? Please provide supporting data and other information to support your comment.

- Should “natural” have some nutritional benefit associated with it? If so, what should be the benefit? What nutrients should be considered? What data are available to support the association between “natural” and a given nutritional benefit, and/or between “natural” and certain nutrients?

- How might we determine whether foods labeled “natural” comply with any criteria for bearing the claim?

Dated: November 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AP06

Ensuring a Safe Environment for Community Residential Care Residents

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Department of Veterans Affairs (VA) regulations governing the approval of a community residential care facility (CRC). We would prohibit a CRC from employing an individual who has been convicted in a court of law of certain listed crimes against a person or property, or has had a finding entered into an applicable state registry

or with the applicable licensing authority concerning abuse, neglect, mistreatment of individuals or misappropriation of property. VA also proposes to require CRCs to develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. The proposed rule would also require CRCs to report and investigate any allegations of abuse or mistreatment. In addition, the proposed rule would require the CRC to screen and monitor individuals who are not CRC residents, but have direct access to a veteran living in a CRC. The revisions would improve the safety and help prevent the neglect or abuse of veteran residents in CRCs. In addition, we propose to amend the rule regarding the maximum number of beds allowed in a resident's bedroom.

DATES: *Comment Date:* Comments must be received by VA on or before January 11, 2016.

ADDRESSES: Written comments may be submitted through www.regulations.gov; by mail or hand-delivery to the Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AP06—Ensuring a Safe Environment for Community Residential Care Residents.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, 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: Dr. Richard Allman, Chief Consultant, Geriatrics and Extended Care Services (10P4G), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420, (202) 461-6750. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: VA is authorized under 38 U.S.C. 1730 to assist veterans by referring them for placement, and aiding veterans in obtaining placement, in CRCs. A CRC is a form of enriched housing that provides health care supervision to eligible veterans not in need of hospital or nursing home care, but who, because of medical, psychiatric and/or

psychosocial limitations as determined through a statement of needed care, are not able to live independently and have no suitable family or significant others to provide the needed supervision and supportive care. Examples of CRC's enriched housing may include, but are not limited to: Medical Foster Homes, Assisted Living Homes, Group Living Homes, Family Care Homes, and psychiatric CRC Homes. CRC care consists of room, board, assistance with activities of daily living (ADL), and supervision as required on an individual basis. The size of a CRC can vary from one bed to several hundred. VA maintains a list of approved CRCs. The cost of community residential care is financed by the veteran's own resources. A veteran may elect to reside in any CRC he or she wants; however, VA will only recommend CRCs that apply for approval and meet VA's standards. Once approved, the CRC is placed on VA's referral list and VA refers veterans for whom CRC care is an option to the VA-approved CRCs when those veterans are determining where they would like to live. VA may provide care to a veteran at the CRC when it is medically appropriate to provide such home-based care. The provision of such home-based care is not contingent upon VA approval of a CRC; a veteran's right to such care exists independent of the veteran's residence in a CRC. Employees of the CRC are not VA employees, and no employment relationship exists between employees of the CRC and VA.

To become approved, a CRC must meet the specified criteria in 38 CFR 17.63, which sets forth standards relating to the physical integrity of the facility, the health care provided at the CRC, the standard of living therein, costs charged directly to veteran residents of the CRC, and other criteria for approval.

VA has authority under 38 U.S.C. 1730(b)(2) to establish criteria for approval of a CRC that will ensure the health, safety and welfare of veterans residing in that facility. Current § 17.63(j) requires CRCs to maintain sufficient, qualified staff on duty who are available to care for residents and ensure the health and safety of each resident. The CRC provider and staff must have adequate education, training, or experience to maintain the facility. However, VA believes that other issues are also important in determining whether a veteran residing in a CRC is receiving an appropriate standard of care. A veteran residing in a CRC is unable to live independently and has no suitable family or significant others to provide the needed supervision and supportive care, and the CRC serves as

that veteran's primary place of residence. VA believes that the CRC should be an environment in which the veteran is physically safe and where the veteran is not at risk of damage, theft, or loss of personal property. To ensure the safety and welfare of veterans residing in CRCs, VA proposes to establish standards that will require CRCs to investigate individuals in CRCs who have direct access to veteran residents and/or veteran resident property.

VA considered several approaches to address the issue of the background and behavior of individuals in CRCs. For example, on the national level, the Patient Protection and Affordable Care Act, Public Law 111–148, established a state grant program for conducting federal and state criminal background checks on direct patient access employees of long-term care facilities and providers that accept Medicare and Medicaid patients (42 U.S.C. 1320a–71). However, not all states participate and it is applicable to only long-term care facilities. A survey of approved CRCs reflects that only a small percentage of those facilities are approved to accept Medicare or Medicaid patients. Another Medicare statute, 42 U.S.C. 1320a–7, excludes an individual from participating in any federal health care program if that individual has been convicted of certain listed crimes. However, a person working in a CRC, or an individual with direct resident access, would not be considered a participant in a federal health care program.

Employees, contractors and volunteers working in VA-operated facilities, such as community living centers or nursing homes, must undergo a background screening as required by Office of Personnel Management (OPM) regulations at 5 CFR parts 731 and 736. If the employee or contractor has access to federally maintained records or databases, the level of scrutiny is greater. CRC staff and others with direct resident access are not federal employees, contractors or volunteers, and do not have access to VA records or databases. Therefore, OPM's federal background screening requirements are inapplicable.

We reviewed state requirements for licensing residential care facilities as well as state screening requirements for employment to work with the elderly or disabled. The states vary in how these issues are addressed. Some require licensing only for facilities that have a minimum number of beds (*i.e.*, five or more beds). Many of the VA-approved CRCs have one to three resident beds. Some state laws and regulations do not

use the term “residential care facility” and it is unclear whether a VA-approved CRC would be covered. Several state licensing laws or regulations do not address hiring requirements. Some do not have any general screening requirements for individuals assigned to duties caring for the elderly or disabled. In those states that do have screening requirements, the level of screening varies from criminal history checks at the county or state level only, to both state and federal-level checks.

While state laws vary on the requirement for background screenings on individuals working with the elderly or disabled, all states maintain a long-term care ombudsman program charged with investigating reports of elder abuse. In addition, all states maintain registries for licensed health care professionals such as nurses and nurse aides to track reports of patient abuse or neglect. However, many individuals employed in a VA approved CRC are not licensed health care professionals and states do not maintain any type of registry that would capture information pertaining to all the types of CRC employees.

Due to these variations, we do not believe we can rely on state law to ensure that veterans can trust and rely on VA-recommended CRCs to provide a certain, uniform minimum level of safety and care. VA believes that all veterans residing in a CRC should have the same level of assurance that a CRC staff member or other covered individual does not have a criminal history, regardless of where that facility is located.

In considering possible national standards, we reviewed existing regulations governing other VA programs. State Veterans Homes are owned, operated, and managed by state governments and provide nursing home, domiciliary, or adult day care to eligible veterans. Regulations governing State Veterans Homes are found at 38 CFR parts 51 through 59. We believe that the State Veterans Home program is meaningfully similar to the community residential care program because it serves a similar veteran population and provides similar services; however, there are two important differences. A State Veterans Home is owned, operated and managed by the state government while a CRC is a privately owned entity. States exercise a layer of control over State Veterans Homes that is not present in CRCs. In addition, persons living in some CRCs who are not obtaining services from that facility regularly interact with CRC residents and sometimes provide services to

residents. State Veterans Homes provide resident services through employees of the state home, many of which are professionals licensed by the state. Nonetheless, VA believes it is appropriate to look to how resident safety and welfare is addressed in the State Veterans Homes program as a guide on how to proceed in the CRC program.

We propose to amend § 17.63 by adding a new paragraph (j)(3) which would require the CRC to develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. This would ensure that each facility has a policy in place to address these issues. In addition, it would serve to inform both employees and CRC residents of the prohibited practices and inform CRC residents about procedures for reporting alleged mistreatment, neglect, and abuse of residents and misappropriation of resident property.

Proposed paragraph (j)(3)(i)(A)(1) would prohibit the CRC from employing an individual who has been convicted by a court of law of abusing, neglecting, or mistreating individuals. VA published a similar rule at § 51.90(c) for State Veterans Homes. That rule has been in place since February 7, 2000, and we believe it has been effective in ensuring the safety of veterans residing in those facilities. We believe a similar standard should be applied to employment in CRCs. The terms “abuse” and “neglect” are defined in § 51.90(b), and would have the same meaning here.

Proposed paragraph (j)(3)(i)(A)(2) would prohibit the CRC from employing individuals who have had a finding entered into an applicable State registry or with the applicable licensing authority concerning abuse, neglect, mistreatment of individuals or misappropriation of property. Examples of applicable state registries include, but are not limited to, state sex offender registries and registries of criminal offenders which are maintained by some states. Typical licensing authorities include, but are not limited to, state boards or agencies that license or certify Registered Nurses (RN), Licensed Practical Nurses (LPN), Certified Nursing Assistants (CNA), nursing aides or medication aides. State laws and regulations typically require employers to report abuse, neglect, mistreatment of individuals or misappropriation of property alleged to have been committed by certain licensed health care professionals. These reports are made part of the relevant State registry, and the registry may contain

information on incidents that were not forwarded to law enforcement for prosecution. VA believes that such information would be relevant to the issue of whether a particular individual should have direct access to a veteran residing in a CRC.

The CRC would be required by proposed paragraph (j)(3)(i)(B) to immediately, meaning no more than 24 hours after the provider becomes aware of the alleged violation, report all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property to the approving official. In proposed paragraph (j)(3)(i)(B)(1)–(6), we would set out the minimum information that must be contained in a report of an alleged violation. The intent of the proposed rule is to place the approving official on notice of any alleged violation so that appropriate follow-up measures can be initiated. Follow-up measures may include contacting veteran residents, ensuring any affected veteran resident receives a medical evaluation from a VA health care provider, or conduct necessary interim monitoring as provided for in § 17.65(a). Proposed paragraph (j)(3)(i)(C) would require the CRC to have evidence that all alleged violations are documented and thoroughly investigated. The facility would be required to prevent further potential abuse while the investigation is in progress. The proposed rule would require that the results of all investigations be reported to the approving official within 5 working days of the incident, and to other officials in accordance with State law, and that appropriate corrective action be taken if the alleged violation is verified. The proposed requirements in paragraphs (j)(3)(i)(B) and (C) are consistent with those already in effect for State Veterans Homes under § 51.90(c).

VA currently receives reports of alleged mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property on an ad hoc basis. The proposed rule would formalize a reporting requirement and would ensure that VA is notified of any such allegation so that appropriate steps can be taken to ensure the safety and health of veterans residing in the CRC. The requirement that the investigation be completed within 5 working days and reported to both VA and other officials in accordance with State law would ensure that the investigation is completed in a timely manner, and that

corrective action is taken to prevent further violations.

We propose in paragraph (j)(3)(i)(D) that employees accused of alleged violations involving mistreatment, neglect, or abuse or misappropriation of resident property, must be removed from all duties requiring direct veteran resident contact during the pendency of the facility's investigation. VA believes that removing such employee from duties involving direct resident contact until the facility completes its investigation is a prudent step to ensure veteran resident safety and to provide assurance to veteran residents that the accused employee would not be allowed direct access to them until the alleged incident is investigated and any necessary corrective steps are taken, if needed.

Proposed paragraph (j)(4) would define the three classes of individuals considered to be employees of the CRC for purposes of this proposed rule. Proposed paragraph (j)(4)(i) would establish that non-VA health care providers at CRCs would be considered employees. Non-VA health care providers may have frequent contact with veteran residents, and are not subject to direct VA control or management. In addition, proposed paragraph (j)(4)(ii) would establish that the term "employee" would include CRC staff who are not health care providers. CRCs employ a variety of personnel that may include, for example, contractors or janitorial staff. These individuals have access to veteran residents, and some may be in a unique position to take advantage of veterans.

Proposed paragraph (j)(4)(iii) would include persons with direct resident access in the definition of "employee." The term "person with direct resident access" would mean an individual living in the facility who is not receiving services from the facility, who may have access to the resident or the resident's property, or may have one-on-one contact with the resident. This could include relatives of live-in staff members. These individuals with direct resident access are most commonly found in medical foster homes, which are typically small CRCs located in a family home, with no more than three consumer residents that are run by certain members of a family, while other family members are not employed by the CRC but continue to live in the home. They do not provide care or services to veteran residents, but may have regular contact with, or access to, veteran residents and their property. We do not include fellow residents who are receiving services from the CRC in the

definition of "person with direct resident access" because we believe that it is inappropriate to consider the background of patients.

In proposed paragraph (j)(5), we would define the term "convicted" for purposes of this proposed rule. An employee would be considered "convicted" of a criminal offense when a judgment of conviction has been entered against the individual by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged. It would also include a finding of guilt against the individual by a Federal, State, or local court. The term "convicted" would also include a plea of guilty or nolo contendere by the individual has been accepted by a Federal, State, or local court. Finally, the term would also encompass participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld. The proposed definition covers the spectrum of outcomes possible when a court of competent jurisdiction finds that a defendant has committed a criminal act. It recognizes that the act that resulted in the conviction, as well as the conviction itself, is relevant to the issue of safety and health of veterans residing in CRCs.

Proposed paragraph (j)(6) would provide that, for purposes of proposed paragraph (j)(3), the terms "abuse" and "neglect" would have the same meaning set forth in 38 CFR 51.90(b). That paragraph describes residents' right to be free from mental, physical, sexual, and verbal abuse or neglect, corporal punishment, and involuntary seclusion. Mental abuse, physical abuse, and sexual abuse are also further defined.

The proposed rule would be enforced through the normal VA inspection and approval process established in § 17.65. This section states that VA may approve a CRC meeting all of the standards in § 17.63 based on the report of a VA inspection and any findings of necessary interim monitoring of the facility. CRCs are inspected by VA at least every 12 months, and an approval is valid for a 12-month period. A CRC may gain provisional approval if that facility does not meet one or more of the standards in § 17.63, provided the deficiencies do not jeopardize the health or safety of residents, and the facility and VA agree to a plan for correcting the deficiencies in a specified amount of time.

If the approving official determines that a CRC does not comply with all of the standards in § 17.63, the facility is

provided notice of the discrepancy and an opportunity for a hearing. Approval of a CRC may be revoked following a hearing as provided for in § 17.71. When revocation occurs, VA ceases referring veterans to the CRC and notifies any veteran residing in that facility of the revocation. Although this proposed rule would not change the process of inspection, approval, or revocation of approval of CRCs established in current 38 CFR 17.61 through 17.72, we have provided the above discussion to show as a practical matter how CRCs would be affected by this proposed rule. The public is invited to comment on whether the proposed new standards in paragraphs (e) and (j) should be enforced in the same manner as every other standard in § 17.63.

The proposed changes to paragraph (j) require a CRC to maintain certain records, develop and implement written policies and procedures prohibiting mistreatment, neglect, abuse of residents, and misappropriation of resident property. The approving VA official may request these records and policies to ensure compliance with VA standards. Current paragraph (i) addresses records that must be maintained by the CRC. We propose to amend paragraph (i) to include the new recordkeeping requirement. We would also reorganize this paragraph to consolidate all resident-related record requirements into a single subparagraph.

Proposed paragraph (i)(1) would state that the CRC must maintain records on each resident in a secure place. Resident records must include a copy of all signed agreements with the resident. Resident records may be disclosed only with the permission of the resident, or when required by law. This mirrors current paragraph (i)(1), (i)(2)(ii), and (i)(3).

In paragraph (i)(2), we would state that the CRC must maintain and make available, upon request of the approving official, records establishing compliance with paragraphs (j)(1) through (3) of this section; written policies and procedures required under paragraph (j)(3) of this section; and, emergency notification procedures. A CRC is required to hire qualified and properly trained staff, per current paragraphs (j)(1) and (2). VA verifies compliance with this standard during routine facility inspections. The proposed rule would prohibit a CRC from employing certain individuals and would require a CRC to develop and implement certain policies and to investigate and document certain allegations of abuse or neglect. The proposed change to paragraph (i) would address the need to maintain records

reflecting compliance with these standards, and would ensure that the approving official may access these records upon request. Current paragraph (i)(2)(i) already requires a CRC to maintain records regarding emergency notification procedures. This proposal would consolidate this with other recordkeeping requirements that are not resident-specific.

In addition, we propose to amend § 17.63(e)(1), regarding the maximum number of beds allowed in a resident's bedroom. Current standards provide that resident bedrooms must contain no more than four beds, and multiresident rooms must provide each resident at least 80 square feet of living space. We propose to limit the number of resident beds in newly established bedrooms in approved facilities and facilities seeking approval. Limiting the number of beds to up to two per bedroom would ensure that veterans receive an appropriate amount of privacy and would appropriately minimize the impact of visits from guests, care providers, etc., on the veteran's quality of life. Under the proposed rule, facilities approved before the effective date of the rule that already have bedrooms with more than two beds would be able to retain that configuration, but could not establish any new bedrooms with more than two beds in a room. Bedrooms in facilities approved after the effective date of the final rule, or newly established bedrooms in facilities approved before the effective date of the final rule, would not be permitted to provide more than two beds. We would allow currently approved configurations because we do not want to negatively impact veteran residents placed in those CRCs who are satisfied with their arrangement.

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 proposed rule includes provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that require approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking to OMB for review. OMB

assigns a control number for each collection of information it approves. VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Proposed § 17.63(i) and (j) would require a collection of information under the Paperwork Reduction Act of 1995. If OMB does not approve the collection of information as requested, VA will immediately remove the provisions containing a collection of information or take such other action as is directed by OMB.

Comments on the collection of information contained in this proposed rule should be submitted to the Office of Management and Budget, Attention: Desk Officer for the Department of Veterans Affairs, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies sent by mail or hand-delivery to: Director, Office of Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or fax to (202) 273–9026; or submitted through <http://www.regulations.gov>. Comments should indicate that they are submitted in response to “RIN 2900–AP06—Ensuring a Safe Environment for Community Residential Care Residents.”

OMB is required to make a decision concerning the collection of information contained in this proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the proposed rule.

VA considers comments by the public on proposed collections of information in—

- Evaluating whether the proposed collections of information are necessary for the proper performance of VA functions, including whether the information will have practical utility;
- Evaluating the accuracy of VA's estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collections of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses.

The collection of information contained in 38 CFR 17.63(i) and (j) is described immediately following this paragraph.

Title: Ensuring a Safe Environment for Community Residential Care Residents.

Summary of collection of information: Current § 17.63(i) addresses recordkeeping requirements for a CRC. Information collection under this paragraph was approved by OMB under OMB control number 2900–0491; however that approval has expired. We propose amending paragraph (i) to address not only the recordkeeping requirements currently in that paragraph, but also recordkeeping requirements under paragraphs (j)(1) through (3).

Paragraph (i)(1) would require the CRC to maintain records on each resident, to include a copy of all signed agreements with the resident. We estimate the annual burden related to this information collection to be one hour per year.

Paragraph (i)(2) would state that the CRC must maintain and make available upon request of the approving official, records establishing compliance with paragraphs (j)(1) and (2). These paragraphs relate to CRC staff requirements, and provide that the CRC must have sufficient, qualified staff must be on duty and available to care for the resident and ensure the health and safety of each resident. The CRC provider and staff must have adequate education, training, or experience to maintain the facility. We estimate that the annual burden related to information collection required to establish that the CRC has sufficient, qualified staff, and that the CRC provider and staff have adequate training and education, would be two hours.

Paragraph (i)(2) would also require the CRC to maintain records related to proposed paragraph (j)(3). Proposed § 17.63(j)(3) would require CRCs to immediately, meaning no more than 24 hours after the provider becomes aware of the alleged violation, report all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property to the approving official. We would require that the report, at a minimum, must include the facility name, address, telephone number, and owner; the date and time of the alleged violation; a summary of the alleged violation; the name of any public or private officials or VHA program offices that have been notified of the alleged

violations, if any; whether additional investigation is necessary to provide VHA with more information about the alleged violation; and contact information for a person who can provide additional details at the community residential care provider, including a name, position, location, and phone number.

We would require the CRCs to document and thoroughly investigate evidence of an alleged violation. The results of all investigations must be reported to the approving official within 5 working days of the incident and to other officials in accordance with State law. It would also require facilities to develop and implement written policies and procedures to prohibit the mistreatment, neglect, and abuse of residents and misappropriation of resident property. The approving VA official may request the facility to produce such written policies and procedures.

The most current data available to VA (Q4 FY2012) reflects that we have 1,293 approved CRCs, 493 of which are Medical Foster Homes at the 1 to 3 bed size. The total number of staff working in these facilities is 5,614. This aggregate number of CRC staff is distributed in CRCs as follows: 2.5 staff for a 1 to 3 bed facility, 4 staff for a 4 to 15 bed facility, 5 staff for a 15 to 26 bed facility and 11 staff for a 26 to 100+ bed facility.

CRCs would be required to report information under this proposed rule when the facility: (1) Has an alleged violation involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property; or, (2) is reporting the results of an investigation into that alleged violation. The CRCs would also be required to document and investigate evidence of any alleged violation. We view the reporting, documenting, and investigating of an alleged incident and the subsequent report of the results of the investigation to be one collection of information, as it focuses on one set of alleged facts and the facility's investigation of those facts.

VA does not currently require CRCs to report to the approving official allegations of resident abuse or neglect. VA surveyed CRC coordinators at the VA medical facilities that approve CRC sponsors. Based on information from CRC coordinators, we believe that VA currently receives fewer than one report of alleged mistreatment, neglect, or abuse, including injuries of unknown source, or misappropriation of resident property from CRCs in any given year. This proposed rule would formalize the reporting and investigation requirement

and we believe this would more likely than not result in an increase in the number of reports of alleged abuse mistreatment, neglect, or abuse, including injuries of unknown source, or misappropriation of resident property per year. However, for purposes of this estimate, we will assume that a CRC will have one incident per year related to an alleged violation involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property; or, reporting the results of an investigation into that alleged violation. The estimated average burden for an alleged violation response is three hours.

All approved CRCs would be required to develop and implement written policies and procedures to prohibit the mistreatment, neglect, and abuse of residents and misappropriation of resident property. On inspection of a CRC, VA would require the facility to produce such written policies and procedures. The written policies would have to be developed once, although it is possible that a promulgated policy could require revision in the future. VA intends to develop sample policies and boilerplate that could be adapted by a CRC to meet the facility's individual requirements. This would decrease the burden of this proposed information collection. VA estimates that the information collection burden on a CRC utilizing a sample policy or boilerplate developed by VA would be two hours.

Finally, paragraph (i)(2) would require the CRC to maintain a record of emergency notification procedures. This is consistent with current § 17.63(i)(2)(i). Once emergency notification procedures are in place, there may be instances in which the CRC may periodically review and modify the existing procedures. We estimate the annual burden of this information collection to be 0.5 hours.

Description of need for information and proposed use of information: VA needs this information to ensure the health and safety of veterans placed in these facilities. In CRCs, where VA involvement is less intensive and to which VA does not provide any payments or services, we believe that information obtained under the proposed rule would provide necessary protection for veteran residents.

Description of Likely Respondents: Operators of CRCs currently listed or that request future listing on VA's approved CRCs referral list.

Estimated Number of Respondents per Year: 1,293 operators of CRCs.

Estimated Frequency of Responses: Once in a 12-month period.

Estimated Average Burden per Response: 8.5 hours.

Estimated Total Annual Reporting and Recordkeeping Burden: 10,990.5 hours.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would be small business neutral as it applies only to those CRCs seeking inclusion on VA's list of approved CRCs. The costs associated with this proposed rule are minimal, consisting of the administrative requirement to develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property; ensure that no employees are employed in contravention to the proposed rule; report to VA any alleged violation involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property; and investigate alleged resident abuse, take steps to prevent further harm, and implement appropriate corrective measures.

A CRC may elect to order background checks on employees from commercial sources or local law enforcement agencies. The cost of an individual background check varies dependent on the vendor, but VA believes the average cost is \$50. VA believes that 75 percent of CRCs are required to, or could obtain, criminal background checks on employees through one or more existing federal or state programs. This includes: (1) The state grant program administered by the Centers for Medicare and Medicaid Services (CMS) for conducting federal and state criminal background checks on direct patient access employees of long-term care facilities and providers (42 U.S.C. 1320a–71); (2) the CMS requirement applicable to facilities receiving Medicare and Medicaid funds; and (3) various state laws or regulations mandating criminal background screening for employment to work with the elderly or disabled. In addition, many CRCs that are currently servicing veterans already, voluntarily, have policies and procedures in place to review the backgrounds of their employees and make employment decisions consistent with this rulemaking as one way to ensure resident safety.

The remaining 25 percent of CRCs (324) would more likely than not opt to

obtain criminal background checks on CRC staff in order to be approved by VA. The median number of staff in CRCs currently approved by VA is five. We estimate the cost that would be incurred for obtaining criminal background checks on CRC staff is \$250 per CRC.

On this basis, the Secretary certifies that the adoption of this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act. Therefore, under 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866 and 13563

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. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action” requiring review by OMB, unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. 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 Web site at <http://www.va.gov/orpm/>, by following the link for VA Regulations Published From FY 2004 to FYTD.

Unfunded Mandates Reform Act

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 expenditures 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 would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles affected by this document are 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; and 64.018, Sharing Specialized Medical Resources.

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. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on November 5, 2015, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Government programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Veterans.

Dated: November 6, 2015.

Jeffrey M. Martin,

Office Program Manager, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, Department of Veterans Affairs proposes to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

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

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

■ 2. Amend § 17.63 by revising paragraph (e)(1) and paragraph (i) and adding paragraphs (j)(3) through (6) to read as follows:

§ 17.63 Approval of community residential care facilities.

* * * * *

(e) * * *

(1) Contain no more than four beds:
(i) Facilities approved before [DATE 30 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE] may not establish any new resident bedrooms with more than two beds per room;

(ii) Facilities approved on or after [DATE 30 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE] may not provide resident bedrooms containing more than two beds per room.

* * * * *

(i) *Records.* (1) The facility must maintain records on each resident in a secure place. Resident records must include a copy of all signed agreements with the resident. Resident records may be disclosed only with the permission of the resident, or when required by law.

(2) The facility must maintain and make available, upon request of the approving VA official, records establishing compliance with paragraphs (j)(1) through (3) of this section; written policies and procedures required under paragraph (j)(3) of this section; and, emergency notification procedures. (Approved by the Office of Management and Budget under control number 2900–XXXX.)

(j) * * *

(3) The community residential care provider must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(i) The community residential care provider must do all of the following:

(A) Not employ individuals who—

(1) Have been convicted by a court of law of abuse, neglect, or mistreatment of individuals; or

(2) Have had a finding entered into an applicable State registry or with the applicable licensing authority concerning abuse, neglect, mistreatment of individuals or misappropriation of property.

(B) Ensure that all alleged violations involving mistreatment, neglect, or

abuse, including injuries of unknown source, and misappropriation of resident property are reported to the approving official immediately, which means no more than 24 hours after the provider becomes aware of the alleged violation. The report, at a minimum, must include—

(1) The facility name, address, telephone number, and owner;

(2) The date and time of the alleged violation;

(3) A summary of the alleged violation;

(4) The name of any public or private officials or VHA program offices that have been notified of the alleged violations, if any;

(5) Whether additional investigation is necessary to provide VHA with more information about the alleged violation; and

(6) Contact information for a person who can provide additional details at the community residential care provider, including a name, position, location, and phone number.

(C) Have evidence that all alleged violations of this paragraph (j) are documented and thoroughly investigated, and must prevent further abuse while the investigation is in progress. The results of all investigations must be reported to the approving official within 5 working days of the incident and to other officials in accordance with State law, and appropriate corrective action must be taken if the alleged violation is verified.

(D) Remove all duties requiring direct resident contact with veteran residents from any employee alleged to have violated this paragraph (j) during the investigation of such employee.

(4) For purposes of paragraph (j)(3) of this section, the term “employee” includes a:

(i) Non-VA health care provider at the community residential care facility;

(ii) Staff member of the community residential care facility who is not a health care provider, including a contractor; and

(iii) Person with direct resident access. The term “person with direct resident access” means an individual living in the facility who is not receiving services from the facility, who may have access to a resident or a resident’s property, or may have one-on-one contact with a resident.

(5) For purposes of paragraph (j)(3) of this section, an employee is considered “convicted” of a criminal offense—

(i) When a judgment of conviction has been entered against the individual by a Federal, State, or local court, regardless of whether there is an appeal

pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged;

(ii) When there has been a finding of guilt against the individual by a Federal, State, or local court;

(iii) When a plea of guilty or nolo contendere by the individual has been accepted by a Federal, State, or local court; or

(iv) When the individual has entered into participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld.

(6) For purposes of paragraph (j)(3) of this section, the terms “abuse” and “neglect” have the same meaning set forth in 38 CFR 51.90(b).

* * * * *

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900–XXXX.)

[FR Doc. 2015–28749 Filed 11–10–15; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0622; FRL–9936–84–Region 9]

Approval and Promulgation of Implementation Plans; California; California Mobile Source Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the California State Implementation Plan (SIP) consisting of state regulations establishing standards and other requirements relating to the control of emissions from new on-road and new and in-use off-road vehicles and engines. The EPA is proposing to approve these regulations because they meet the applicable requirements of the Clean Air Act and are relied upon by various California plans intended to provide for the attainment or maintenance of the national ambient air quality standards.

DATES: Any comments must arrive by December 14, 2015.

ADDRESSES: Submit comments, identified by docket number [EPA–R09–OAR–2015–0622], by one of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the on-line instructions.