

Act. This guidance document has been updated to reflect these changes.

On September 12, 2005, FDA issued the first edition of a guidance entitled "Questions and Answers Regarding the Establishment and Maintenance of Records." This document is the fifth edition of that guidance and is updated to reflect changes to the FD&C Act made by FSMA. This guidance is intended to provide individuals in the human and animal food industries with an updated overview of FDA's access to records. It provides practical information by answering common questions that cover a range of topics, including who is subject to records requirements, the scope of records retention and availability requirements, and the consequences of failing to establish and maintain required records or failing to make required records available to FDA. This guidance is being issued consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115) as a level 1 guidance. The Agency will accept comments, but it is implementing this document immediately, in accordance with § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate. The Agency made this determination because this guidance simply reflects the statutory changes made by section 101 of FSMA to sections 414 and 704 of the FD&C Act and seeks to remove any confusion that might arise due to the existence of a guidance document that is inconsistent with the FD&C Act and its implementing regulations. In addition, much of this guidance remains the same as the guidance issued in September 2006.

This guidance represents the Agency's current thinking on its authority to access and copy records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to information collection provisions found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that the collection of information in § 1.361 is exempt from OMB review under 44 U.S.C. 18(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to

which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA guidance document by using the Web sites listed previously to find the most current version of the guidance.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 59

RIN 2900–AN77

Due Date of Initial Application Requirements for State Home Construction Grants

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) regulations concerning the calendar date by which VA must receive an initial application for a State Home Construction Grant in order for the application to be included on the priority list for the award of grants during the next fiscal year. We require that initial application materials must be received by VA no later than April

15, instead of August 15, of the year before the fiscal year in which the application would be considered for inclusion on the priority list for the award of grants. We require certification of State matching funds to be submitted no later than August 1, instead of August 15, in order for the project to be placed in priority group 1 of the priority list for the next fiscal year. The purpose of these changes is to ensure that VA has sufficient time to process all applications received and timely prepare the priority list, so that we can accurately notify States that VA intends to select and fund particular projects. We also make technical revisions to conform our regulations to these revisions.

DATES: This final rule is effective March 26, 2012.

FOR FURTHER INFORMATION CONTACT:

Vernon Wilkes, State Veterans Homes (10NA5), 1717 H Street NW., Washington, DC 20006, (202) 266–4617. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 8131 through 8138, VA is authorized to award grants to assist States in constructing, remodeling, altering, or expanding State home facilities that will furnish specified types of care to veterans. VA has implemented this statutory authority at 38 CFR part 59.

Under 38 U.S.C. 8135, States that wish to receive assistance for a State home construction project (or acquisition of an existing facility to be used as a State home facility) must submit an application that includes certain information and documentation described in the statute. VA has implemented the application requirement in current § 59.20(a), which requires that applicants seeking inclusion on the priority list for grants awarded during the next fiscal year submit to VA an original and one copy of a completed VA Form 10–0388–1 and all information, documentation, and other forms specified by VA Form 10–0388–1. Under current § 59.20(c), VA encourages the submission of the application by April 15 but considers any application submitted before August 16 for inclusion on the priority list. VA maintains the "priority list" pursuant to current 38 CFR 59.50. Additionally, under current § 59.70(b), VA requires a State to commit funds for a project before August 16 in order for that project to be eligible for inclusion in priority group 1 of the priority list for the next fiscal year.

On March 1, 2011, VA published a proposed rule to improve the clarity and efficacy of the application process and

to address certain administrative challenges presented by the current rules. 76 FR 11187 (Mar. 1, 2011). We proposed adopting April 15 as the due date for applications, including matching funding. We provided a 60-day comment period during which we received eight comments from State departments of veterans affairs and State veterans homes and a comment from the National Association of State Veterans Homes. All of the commenters raised similar or identical concerns, which we address below. We are grateful for their submissions and, after careful deliberation, make one change to the final rule based on these comments.

First, several commenters assert that they have consistently treated the April 15 date as a "preapplication" date and acknowledge that they complete as much of the application as possible on or before that date. However, they argue that it is impossible to meet an April 15 deadline for matching funds because the fiscal year for most States begins on July 1, which is after that deadline. To address this concern, the final rule adopts a separate, later, deadline for the official certification of matching funds. Under the final rule, the application must be received no later than April 15. If official certification of the matching funds is received on or before August 1, the State may be included in priority group 1.

This will allow VA to review the submissions and establish each application in priority groups 2 through 7 (which mirror the sub-priorities in priority group 1 with the distinction that projects in priority group 1 have State matching funds while those in priority groups 2 through 7 lack these resources). When a State is able to provide documentation of State matching funds, the application will be placed in the appropriate position in priority group 1. Should a State be unable to document matching funds by the new August 1 deadline, the project will be placed in one of groups 2 through 7 for the following fiscal year.

Some commenters argue that the burden of filing the application itself, not just the matching-funds requirement, would be impossible to meet before April 15. Previous experience is that most States already submit preapplication materials on or before April 15, as acknowledged by the commenters themselves, and thus, we do not think that there will be a new significant burden. The items required on the VA Form 10-0388-1 are generally administrative information (such as identifier numbers) and the schematics of the project. Schematics generally require an aerial view of the

site of the project, a floor plan, and a rendering of the exterior of the building. Although these may require some financial expense, we believe that the cost is usually between \$6,000 and \$10,000. In any event, it is never a significant expense in relation to the cost of the project itself, which is usually over \$30 million. We do not believe that it should be necessary to wait for a State legislature to authorize the expense or time for producing these application materials.

The commenters challenged VA's need for the additional review time, citing the impact of the American Recovery and Reinvestment Act of 2009 (ARRA) on the previous grant cycle asserting that it resulted in an anomalously high number of applications. We acknowledge that the ARRA increased the 2010 workload but maintain that there is a need for additional review time in general, based on the uniqueness of each fiscal year, the complexity of the projects, and the need for extensive detailed and careful review of each application. In fact, we had begun reassessing the August 15 due date before Fiscal Year 2010. Adoption of the proposed April 15 application due date, while allowing States to submit documentation of matching funds by August 1, will allow VA to provide due diligence in the review and prioritization process, while maximizing the States' opportunity to obtain and document matching funds to secure a position in priority group 1.

Several commenters recommended delaying publication of the priority list rather than altering the due date. We appreciate the flexibility recommended by these parties but note that release of the priority list is determined by the time federal budget funds are appropriated. Regardless of the ultimate date the budget is finalized, VA strives to publish the priority list in a timely manner and will continue to do so in an effort to provide quick, efficient distribution of and maximum access to available funds.

The commenters also argue administrative inconvenience. However, the initial application materials are not overly burdensome, and requiring the earlier deadlines will help VA ensure the timely delivery of funds to worthy State projects. Because most applications are already received by April 15, this date is reasonable, and allowing for the August 1 date for the certification of matching funds addresses the administrative needs of the States.

Finally, commenters objected to VA's rulemaking as being based solely on the administrative needs of VA staff, at the

expense of America's veterans. VA strives diligently to remain veteran-centric in all of its programs. Clarification of the due date and the technical changes proposed in this amendment are designed to mirror current practice and to facilitate a thorough and complete review of grant applications prior to funding, in an effort to minimize program delays and make space in the State homes available to our veterans as quickly as possible. VA has always initiated review of proposals upon receipt, which in most cases has been by the April 15 date cited in § 59.20. However, VA's review of these grants and their construction plans necessitates numerous internal concurrences; communications with the States for clarification of the application materials; development and adoption of memorandums of understanding for each project; and other significant, time-consuming, relevant processes. Each proposal is unique and may have special issues, including terrain, access, potential for natural disaster, facility measures, varying codes and local requirements, etc. VA staff assesses new construction as well as renovations to facilities of various ages, under an assortment of State and national construction and safety standards, to ascertain that each element of the application is thorough, complete, and current. Requiring this detailed review prior to prioritization and funding ensures that the project is "shovel ready" when funds become available. This, in turn, helps ensure that VA funds projects that will be ready, on time, for waiting veterans.

Acknowledging the effort the States have historically made to submit applications by the April 15 date to secure their position on the priority list, we believe formal adoption of an April 15 deadline, with the August 1 date for documentation of matching funds for placement in priority group 1, will help VA and the States and, most importantly, serve the needs of veterans by improving existing space and making new space available for eligible veterans at the earliest possible moment.

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 an 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 given year. This rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

Although this document contains provisions constituting collections of information, at 38 CFR 59.20, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), no new or revised collections of information are associated with this rule. The information collection requirements for § 59.20 are currently approved by OMB and have been assigned OMB control number 2900–0661.

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,” which requires review by the Office of Management and Budget (OMB), 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 regulatory action have been examined and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Regulatory Flexibility Act

The Secretary hereby certifies that this final 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. The rule affects States and has no impact on any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are as follows: 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

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. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on November 14, 2011, for publication.

List of Subjects in 38 CFR Part 59

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

Dated: February 17, 2012.

Robert C. McFetridge,

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

For the reasons set forth in the preamble, VA amends 38 CFR part 59 as follows:

PART 59—GRANTS TO STATES FOR CONSTRUCTION OR ACQUISITION OF STATE HOMES

■ 1. Revise the authority citation for part 59 to read as follows:

Authority: 38 U.S.C. 101, 501, 1710, 1742, 8105, 8131–8137.

■ 2. Amend § 59.20 by:

■ a. Revising paragraph (c).

■ b. Removing “August” from paragraph (d) and adding, in its place, “April”.

■ c. Adding an information collection approval parenthetical after the authority citation at the end of the section.

The revision and addition read as follows:

§ 59.20 Initial application requirements.

* * * * *

(c) The items requested under paragraph (a) of this section must be received by VA no later than April 15 in order for VA to include the application on the priority list for the award of grants during the next fiscal year. *See* § 59.50, Priority List.

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(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0661)

■ 3. Amend § 59.50 by removing “August” from the introductory text of paragraph (a) and adding, in its place, “April”.

■ 4. Amend § 59.70 by removing “August 15” from paragraph (b) and adding, in its place, “August 1”.

[FR Doc. 2012–4234 Filed 2–22–12; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

48 CFR Parts 519 and 552

[GSAR Amendment 2012–02; GSAR Case 2011–G502; (Change 54) Docket 2012–0003, Sequence 1]

RIN 3090–AJ24

General Services Administration Acquisition Regulation; Acquisition-Related Thresholds

AGENCIES: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: GSA is issuing a final rule amending the General Services Administration Acquisition Regulation (GSAR) to update the acquisition-related thresholds in two GSAR clauses.

DATES: *Effective Date:* March 26, 2012.