

Supporting Statement

A. Clearance for Revised Pre-grant Data Request Form

On June 3, 2004, OMB approved a “pre-grant data request form” used by the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS). The form is designed to collect data from health care providers who have requested certification to participate in the Medicare program. (See OMB Number: 0990-0243; Expiration Date: 06/30/2007). This civil rights compliance determination is an essential component of HHS’ decision to grant or deny certification and must be made prior to the Department’s final notification of its decision to the provider.

OCR is now requesting approval of a pre-grant data request form that is very similar to that submitted and approved in 2004. There were no substantive changes made in this Medicare Certification Civil Rights Information Request Form. However, a few technical changes were made to make the form easier to read and understand (for example, the checklist box format was omitted. Also, there are now eleven questions instead of twelve questions because questions 6 and 7 regarding Limited English Proficiency (LEP) were combined, into question 6. While OCR has also revised the form to add two subparts to questions 6 and 7, these too are primarily technical in that they clarify the respondents’ obligation with respect to those questions.

The form still requests information necessary to determine whether a health care provider seeking certification is in compliance with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 and the Age Discrimination Act of 1975. Specifically, the form’s questions pertain to the provider’s nondiscrimination policies and procedures on the basis of race, color, national origin, disability, and age (Attachment A).

B. Justification

1. Legal /Administrative Requirement

The Centers for Medicare and Medicaid Services (CMS) require health care providers to meet certain legal requirements in order to participate in the Medicare Part A program established by Title XVIII of the Social Security Act. Those legal requirements include ensuring that health care providers receiving Federal financial assistance from the Department of Health and Human Services do not deny benefits or services to qualified persons based on race, color, national origin, disability, or age. OCR conducts reviews of such providers to determine compliance with the requirements of the following statutes and regulations:

- o Title VI of the Civil Rights Act of 1964 (Title VI) Pub.L. 88-352, 42 U.S.C. Section 2000d-1 et seq., and its implementing regulation, Title 45 Code of Federal Regulations (CFR) Part 80, which prohibit discrimination on the grounds of race, color, or national origin by recipients of Federal financial assistance. This requirement encompasses the requirement for recipients to

take reasonable steps to provide meaningful access to persons who are limited English proficient (LEP). See Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (2003).

- o Section 504 of the Rehabilitation Act of 1973 (Section 504), Pub.L. 93-112, as amended by Pub. L. 93-516, 29 U.S.C. Section 794, and its implementing regulation, Title 45 CFR Part 84, which prohibit discrimination on the basis of disability by recipients of Federal financial assistance.
- o Age Discrimination Act of 1975, Pub. L. 94-135, 42 U.S.C. Section 6101 *et seq.*, and its implementing regulation, Title 45 CFR Part 91, which prohibit discrimination on the basis of age by recipients of Federal financial assistance.

2. How the Information Will Be Used

To ensure adherence to the statutory requirements listed above, pre-grant reviews are requested when health care providers such as hospitals, nursing homes and home health agencies apply to participate in the Medicare program. When a provider seeks Medicare certification, OCR conducts a pre-grant review to determine whether the provider will be able to comply with Title VI, Section 504, and the Age Discrimination Act. Such reviews are an effective means of working with health care providers because potential civil rights concerns can be identified prior to receipt of Federal financial assistance. The technical assistance available to recipients on the OCR website helps providers take steps to comply with their obligations to refrain from prohibited discrimination.

This approach is efficient and practical because it promotes voluntary compliance, while decreasing the need for more in-depth Federal complaint investigations and compliance reviews that impose greater costs, both on the recipient and on OCR.

The information received from the facility provides OCR with a basic understanding of how the program is administered. OCR conducts an analysis addressing the following requirements:

Assurance of Compliance. 45 CFR 80.4(a), 45 CFR 84.5 and (45 CFR 91.33 require that an assurance of compliance (Form HHS-690) be submitted, which state that the facility will comply with all the requirements of the aforementioned statutes and their implementing regulations.

Policies of Nondiscrimination. 45 CFR 80.6(d), 45 CFR 84.8, and 45 CFR 91.32 require that the facility have a written policy of nondiscrimination on the basis of race, color, national origin, disability and age. Because the regulations requiring dissemination of such policies

vary according to the particular regulatory authority, the provider is referred to a link to the specific regulations, and provided with a sample Nondiscrimination Policy (Attachment B).¹

Language Assistance. 45 CFR 80.3(b)(2) prohibits the provider from utilizing criteria or methods of administration that have the effect of subjecting individuals to discrimination because of their race, color, or national origin. This requirement encompasses the requirement for recipients to take reasonable steps to provide meaningful access to persons who are limited English proficient (LEP). See Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (2003). The guidance recommends that facilities, in describing the language assistance measures to be used to ensure effective communication between providers and LEP persons, review the number of LEP persons in its service area, the frequency of contact with LEP persons, the nature of services provided and the costs and resources available to the facility. It further explains that these factors should be considered for both oral and written communication with LEP persons. The provider is provided with a sample Policy for Communication with Persons with Limited English Proficiency (Attachment C).

Auxiliary Aids. 45 CFR 84.52(d) requires the facility to provide auxiliary aids to persons with impaired sensory, manual or speaking skills, where necessary to provide such persons an equal opportunity to benefit from the service in question. The provider is provided with a sample Policy for Auxiliary Aids and Services for Persons with Disabilities (Attachment D), and a sample Section 504 Notice of Program Accessibility (Attachment E).

Section 504 Data. 45 CFR 84.7 requires facilities that employ 15 or more persons to designate a responsible employee to coordinate compliance with the Section 504 regulation; further the facility must provide a copy of its grievance procedure for handling disability discrimination grievances. The provider is provided with a sample Section 504 Grievance Procedure (Attachment F).

Age Distinctions. 45 CFR 91.31 requires the facility's policies and practices to be free from restrictions of services based on age, and an explanation must be provided concerning any exceptions/exemptions that may apply.

The benefits of the pre-grant review investigation process include:

- o Increased recipient awareness and cooperation - The pre-grant review enables recipients to establish appropriate policies and procedures or correct potential noncompliance in a voluntary context. Because of the self-corrective and direct technical assistance nature of the pre-grant review, OCR's experience has been that recipients are generally cooperative and view the

¹ For instance, the most specific regulatory provision concerning notice under Section 504 and its implementing regulations, 45 CFR 84.8, requires steps to notify participants, beneficiaries, applicants and employees (including those with impaired vision or hearing), and unions and professional organizations holding collective bargaining or professional agreements with the recipient that the recipient does not discriminate on the basis of disability in violation of Section 504 and the regulation.

activity as an informative and positive step that can help them avoid potential civil rights compliance concerns in the future.

Working with Medicare providers during a pre-grant review, OCR can develop on-going relationships that can have residual positive results in service delivery and marketing among other business groups. For example, once recipient agencies have contacted and worked cooperatively with groups representing persons with disabilities, the agencies are more likely to seek help from these groups if subsequently they need assistance in resolving compliance problems. This cooperative working relationship can enhance compliance and forestall formal complaints to OCR.

- o Reduced Provider Burden- In conducting a complaint investigation or compliance review of a health care or social service provider, OCR determines whether a pre-grant was performed. In many instances, the procedure decreases the burden on the recipient since the pre-grant and corrective actions, as necessary, may reduce or eliminate the need for a formal investigation involving interviews, examination of records, collection and submission of data associated with issues already addressed through a recent pre-grant review certification process.

To further reduce provider burden in completing the pre-grant process, OCR has developed several national agreements with health care corporations. These agreements are designed to expedite the civil rights pre-grant clearance process by implementing a practice whereby all of a corporation's national policies and procedures are reviewed and approved at OCR's headquarters' level. Subsequent to such approval, only local facility-specific information is reviewed by OCR for civil rights compliance during a pre-grant review.

3. Use of Improved Information Technology/Technical or Legal Obstacles to Reducing Burden.

OCR currently provides a website www.hhs.gov/ocr/crclearance.html that allows covered entities immediate access to the pre-grant clearance package and technical assistance material. Providing ready access to technical assistance to recipients in completing the pre-grant review has served to both encourage compliance and avoid circumstances in which providers deploy measures that might be less effective and more costly than necessary to achieve compliance.

4. Efforts to Identify Duplication and Why Similar Information Already Available Cannot be Used or Modified to Serve Relevant Program Purposes

The information requested is not otherwise available. Title VI, Section 504, and the Age Discrimination Act do not otherwise require generation or production of nondiscrimination policies and procedures on the basis of race, color, national origin, disability and age for submission to any other Federal entity or authority.

5. Small Business-Minimizing Burden

The pre-grant review imposes a lesser burden on small providers than on larger HHS recipients, since generally, the smaller the provider and the fewer services provided, the narrower the scope of inquiry will be in conducting a pre-grant review.

6. Consequence if Collection were Not Conducted or Conducted Less Frequently

If the pre-grant collection of relevant information is not conducted, OCR cannot ensure that a Medicare provider facility will be in compliance with applicable HHS nondiscrimination statutes and regulations. As described above, a pre-grant review results in increased recipient awareness and cooperation and reduces or potentially may eliminate the need for a formal investigation, thus reducing the potential provider burden that may result if OCR has to conduct a complaint investigation or compliance review.

7. Explain Any Special Circumstances that Require the Collection to be Conducted in a Manner Inconsistent with Guidelines

Recordkeeping Requirements

Records produced in conjunction with the pre-grant data request, such as a provider's Assurance of Compliance (Form 690), non-discrimination and other civil rights policy statements, Section 504 Grievance Procedure, and procedures for effective communication with persons of limited-English proficiency, are usually items only 1-3 pages in length and are maintained in the normal course of business.

Further, recordkeeping requirements are reduced by the revised data request, as the Section 504 self-evaluation requirement has been deleted. The decision to delete this requirement was based on the general consensus of the National Pre-grant Workgroup in conjunction with a recommendation from DOJ and from OCR's General Counsel Office that the self-evaluation requirement in Section 504 should be interpreted as time-limited.

8. Consultation with Persons Outside the Agency

A 60-day Federal Register Notice was published on February 26, 2007, vol. 72, No. 69: pp 18253. There were no public comments.

9. Decision to Provide Any Payment or Gift to Respondents.

Not applicable.

10. Assurance of Confidentiality

Not applicable.

11. Questions of a Sensitive Nature

Not applicable.

12. Estimates of Burden

Fiscal Year	Est. Number of Respondents	Est Average Burden Per Respondent	Total Burden Hours
2007	3,900	15 hours	58,500

Recipients subject to pre-grant reviews vary greatly in size, and many provide specialized or limited health services. The complexity of the pre-grant review and the amount of time needed for completion is greater for those facilities providing a wider range of services.

We estimate that it would take an average of 15 hours per respondent to complete the pre-grant data request. Based on data collected by OCR's Regional staff, the average time to complete the data request can range from 4 hours to 80 hours, depending on the size of the facility and the types of services provided. The current blended estimate of 15 hours per respondent represents a small reduction from 16 hours estimate in FY 2004. This results in a total decrease in burden hours of 5,500.

OCR experienced a cumulative increase in the pre-grant review workload each year from FY 2000 to FY 2005, averaging 4,000 cases per year at the time OCR submitted its 2004 request for Clearance for Revised Pre-grant Data Request Form. OCR saw a small decrease in the 2006 workload to 3,858 cases, and projects that the workload number in FY 2007 will remain approximately the same in FY 2007

Annual Numbers of Respondents	Average Hours per Respondent	Total Burden-Hours	Estimated Cost/Hour*	Projected Total	Cost Per Facility
3,900	15	58,500	\$37.00	\$2,164,500	\$555

The average cost of \$555 per facility responding to the pre-grant data request is calculated based on the average salaries of three categories of health care workers (i.e., medical and health services managers, registered nurses, and all other health professionals, para-professionals and technicians). These categories are representative of those who would be responding to the pre-grant data request. The salaries were taken from the Bureau of Labor Statistics (BLS) Occupational Employment Statistics for 2005 and adjusted for inflation. Using the average of salaries for these three categories of workers, both benefits and overhead costs were added based

on the Office for Civil Rights' (OCR) own budget experience. The hourly cost to facilities, therefore, is based on salaries adjusted for inflation plus benefits and overhead charges. This is the same cost allocation method that OCR has used to estimate the government cost of this collection.

13. Expense Cost:

Not applicable.

14. Estimated Annualized Cost:

The government annualized cost estimate of \$2,134,000 is based on the proportion of the Office for Civil Rights' (OCR) compliance staff time estimated as being allocated to pre-grant work during FY 2007. The allocation of investigative time is based on the relative number of hours required to complete each type of OCR compliance activity (e.g., complaints, post-grant reviews, outreach and pre-grant reviews). OCR's budget estimates that just over 7 percent of compliance staff time is allocated to pre-grants. Based on the salaries and benefits for compliance staff and OCR's associated overhead, OCR has estimated the total funds allocated to conduct pre-grant reviews. Given a workload of 3,900 pre-grants, the estimated cost of the government's review of the average pre-grant is \$547.

15. Reasons for Changes in Burden

Since the last clearance request in 2004 for its Pre-grant Data Request Information Form, the Office for Civil Rights (OCR) has made a small reduction in its estimate to the average burden per respondent from 16 hours to 15 hours. This reduction of one hour is based on OCR's continued intensive technical assistance efforts that it provides to respondents, and the increased use of technology by OCR and its respondents.

Our review of respondents' submission over the past three years showed that they were submitting their responses to data requests more completely and in a more timely. We attribute these changes to the fact that more recipients have accessed the OCR website to obtain our pre-grant package and technical assistance materials.

Not applicable.

16. Publication of Results

Not applicable.

17. If seeking approval to not display the expiration date for OMB approval of the information collection.

Not applicable.

18. Exception to the Certification statement.

Not applicable.

19. Collections of Information Employing Statistical Methods

Not applicable. The pre-grant review described above in part A does not require nor lend itself to the application of statistical methods.

ATTACHMENTS

- A. Civil Rights Information Request for Medicare Certification
- B. Sample Nondiscrimination Policy
- C. Sample Policy for Communication with Persons with Limited English Proficiency
- D. Sample Policy for Auxiliary Aids and Services for Persons with Disabilities
- E. Sample Section 504 Notice of Program Accessibility
- F. Sample Section 504 Grievance Procedure