DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 Part CFR 505

[CMS–1320–P]

RIN 0938–AN93

Medicare Program; Health Care Infrastructure Improvement Program; Forgiveness of Indebtedness

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) by establishing the loan forgiveness criteria for qualifying hospitals who receive loans under the Health Care Infrastructure Improvement Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 29, 2005.

ADDRESSES: In commenting, please refer to file code CMS–1320–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1320–P, P.O. Box 8020, Baltimore, MD 21244–8020.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Tzvi Hefter, (410) 786–4487 (For information on the loan terms).

Melinda Jones (410) 786–7069 (For information on loan forgiveness criteria).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist CMS in fully considering issues and developing policies. You can assist CMS by referencing the file code CMS–1320–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended Title XVIII of the Social Security Act (the Act) to establish section 1897 of the Act, the Health Care Infrastructure Improvement Program (Loan Program). Section 1897 of the Act authorizes the Secretary of the U.S. Department of Health and Human Services (Secretary) to establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of eligible projects.

Section 1897(c) as amended by Section 6045 of the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005 (Tsunami Relief Act of 2005) (Pub. L. 109–13) defines a qualifying hospital as a hospital or entity that is engaged in research in the causes, prevention, and treatment of cancer; and is designated as a cancer center by the National Cancer Institute (NCI) or is designated by the State legislature as the official cancer institute of the State and such designation by the State legislature occurred prior to December 8, 2003. Section 1897(c)(3) of the Act also specifies that an entity has the same meaning as specified in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from tax under section 501(a) of the Code; has at least one existing memorandum of understanding or affiliation agreement with a hospital located in the State in which the entity is located; and retains clinical outpatient treatment for cancer on site as well as lab research and education and outreach for cancer in the same facility.

Section 1897(d) of the Act specifies that an eligible project is a project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

Section 1897(f) of the Act states that the Secretary may forgive a loan provided to a qualifying hospital, under terms and conditions that are analogous to the loan forgiveness provision for student loans under part D of title IV of the Higher Education Act of 1965, (20 U.S.C.1087a *et seq.*). However, the Secretary shall condition such forgiveness on the establishment by the hospital of—(1) An outreach program for cancer prevention, early diagnosis and treatment that provides services to a substantial majority of the residents of the State or region, including residents of rural areas; (2) an outreach program for cancer prevention, early diagnosis,

and treatment that provides services to multiple Indian Tribes; and (3) unique research resources (such as population databases); or an affiliation with an entity that has unique research resources.

Also, section 1897(h) of the Act states that the Secretary shall submit to Congress a report on the projects for which loans are provided under this section and a recommendation as to whether Congress should authorize the Secretary to continue loans under this section beyond fiscal year 2008.

Furthermore, prior to the Tsunami Relief Act of 2005, section 1897(g)(1) of the Act appropriated $200,000,000 to carry out the loan program. The funds allocated for the loan program are to remain available during the period beginning on July 1, 2004, and ending on September 30, 2008. However, the Congress rescinded $58,000,000 leaving $142,000,000 available for the loan program. The statute also states that not more than $2,000,000 can be used for the administration of the loan program for each of the fiscal years (that is, 2004 through 2008). No administrative funding was used in fiscal year 2004.

In addition, section 1897(i) of the Act as amended by section 6045(b) of the Tsunami Relief Act of 2005 states that there shall be no administrative or judicial review of any determination made by the Secretary under this section.

II. Provisions of the Proposed Regulation

Section 1897 of the Act authorizes the Secretary to establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of qualifying projects. Section 1897 of the Act also requires that criteria be established for—(1) selecting among qualifying hospitals that apply to participate in the loan program; and (2) the forgiving of indebtedness (hereinafter referred to as loan forgiveness). This proposed rule would establish the loan forgiveness criteria for qualifying hospitals that participate in the loan program. We are publishing a separate rulemaking document for selecting qualifying hospitals to participate in the Health Care Infrastructure Improvement program (loan program).

A. Conditions for Loan Forgiveness (Proposed § 505.13)

[If you choose to comment on issues in this section, please include the caption ''Conditions for Loan Forgiveness'' at the beginning of your comments.]

Section 1897(f) of the Act authorizes the Secretary to forgive a loan provided to a qualifying hospital under terms and conditions that are analogous to the loan forgiveness provision for student loans under part D of title IV of the Higher Education Act of 1965 [20 U.S.C. 1087a *et seq.*). The student loan program specifies that in order to be eligible for loan forgiveness, borrowers are required to satisfy certain conditions, such as, completing a service obligation which satisfies certain terms and conditions as determined by the Secretary. Therefore, we propose to apply the loan forgiveness model of the student loan program and require that a hospital complete a service obligation which satisfies certain terms and conditions in order to qualify for loan forgiveness. That is, we are proposing that to fulfill the service obligation borrowers must meet the loan forgiveness conditions discussed herein that are based on section 1897(f) of the Act which states that the Secretary shall condition such forgiveness on the establishment by the hospital of—(1) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas; (2) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and (3) unique research resources (such as population databases); or an affiliation with an entity that has unique research resources.

In addition, we are proposing that the qualifying hospital must submit a written request for loan forgiveness to CMS by the effective date of the final rule.

Furthermore, we are proposing specific criteria that a qualifying hospital must follow to meet the conditions for loan forgiveness.

B. Plan Criteria for Meeting the Conditions for Loan Forgiveness (Proposed § 505.15)

[If you choose to comment on issues in this section, please include the caption ''Criteria for meeting the conditions for loan forgiveness'' at the beginning of your comments.]

In order to qualify for loan forgiveness, the qualifying hospital must meet the specific criteria proposed at § 505.13. We would organize the loan forgiveness criteria into 3 domains. These domains are consistent with the section 1897(f)(A),(B), and (C) of the Act. The three proposed domains are—(1) Outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas; (2) outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and (3) unique research resources (such as population databases); or an affiliation with an entity that has unique research resources.

In proposed § 505.3, we would define ''outreach programs'' as formal cancer programs for teaching, diagnostic screening, therapy or treatment, prevention, or interventions to enhance the health and knowledge of their designated population(s). Likewise, we are proposing to define ''unique research resources'' as resources that are used for the purpose of discovering or testing options related to the causes, prevention, and treatment of cancer. We are soliciting comments on these definitions.

We are proposing at § 505.13(c) that the qualifying hospital must submit to CMS by the timeframe specified by the Secretary the following: (1) A written request for loan forgiveness; (2) a plan describing how the qualifying hospital would establish, implement or maintain existing outreach programs for its targeted populations; and (3) how it would establish or maintain existing unique research resources over the loan deferment period. We propose to make that timeframe 60 days after the publication of the final rule.

We are also proposing in § 505.15 that the qualifying hospital designate in its plan, the population(s) for which it would target its outreach programs and be held accountable in the assessment for loan forgiveness. The qualifying hospital's target populations for the outreach programs must include a substantial majority of the residents of a State or region, including residents of rural areas and multiple Indian tribes that the qualifying hospital services. We are proposing that the qualifying hospital must describe how it would designate the targeted populations to include residents of rural areas. CMS also proposes that for a list of Indian tribes eligible for inclusion in the target population, qualifying hospitals would refer to the notice on ''Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs.'' The most recent notice was published in the **Federal Register** on December 5, 2003 (68 FR 68180). Qualifying hospitals should use this list when designating the target population for outreach programs servicing multiple Indian tribes in its plan to CMS.

We invite public comments on the type of information that must be included in the plan and the timeframe

for a qualifying hospital to submit its plan to CMS. We are also soliciting comments on whether we should provide more specific criteria for the qualifying hospital to use in defining its targeted populations.

We believe that 60 days after the final rule publication date is reasonable time for qualifying hospitals intending to apply for loan forgiveness to prepare and submit their initial plan, since the loan deferment period is 60 months after notification of acceptance in the program and the qualifying hospital would be assessed on its performance during the loan deferment period.

Furthermore, we believe that requiring the qualifying hospitals to submit a plan in which they would determine the targeted population, the types of cancers (that is, the cancer types to be considered), goals for improving prevention, diagnosis, and treatment, and the measures to track their progress in reaching the goals provides flexibility to the qualifying hospitals as they develop, implement, or maintain their outreach programs.

We also believe that it is appropriate to request this level of detail from the qualifying hospitals because section 1897(h) of the Act requires the Secretary to submit a report to the Congress before fiscal year 2008. The report must indicate the projects for which loans are provided under this section and recommend whether the Congress should authorize the Secretary to continue loans under beyond fiscal year 2008. Receiving this information from the qualifying hospitals is necessary for the Secretary to make a fully informed recommendation to the Congress.

1. Domain 1: Outreach Program That Services a Substantial Majority of the Residents of a State or Region, Including Residents of Rural Areas

We are proposing that the qualifying hospitals plan include a description of how it would establish, develop, implement, or maintain an existing outreach program that services a substantial majority of the residents of a State or region, including residents of rural areas for cancer prevention, early diagnosis, and treatment over the loan deferment period including proposed intervention approaches. The plan must—(1) identify the target population in accordance with section 1897(f)(A) of the Act; (2) identify the cancer type(s) that would be included in the outreach program and how they were determined; (3) describe the intervention approaches it would consider using in its outreach program; (4) propose goals for improvement in each of the three areas (that is, prevention, early diagnosis, and treatment) during the loan deferment period for each cancer type identified; and (5) identify measures that would be used to track annual progress in meeting the proposed goals in the three areas for each cancer type identified.

2. Domain 2: Outreach Program That Services Multiple Indian Tribes

We are proposing that the qualifying hospitals plan include a description of how it would establish or develop, implement, or maintain an existing outreach program that services multiple Indian Tribes for cancer prevention, early diagnosis, and treatment over the loan deferment period including proposed intervention approaches. The plan must—(1) designate the target population using the notice on ''Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs'' published in the **Federal Register** on December 5, 2003 (68 FR 68180), in order to meet the requirements at section 1897(f)(B) of the Act; (2) identify the cancer type(s) that would be included in the outreach program and how they were determined; (3) describe the intervention approaches it would consider using in its outreach program; (4) propose goals for improvement in each of the three areas (that is, prevention, early diagnosis, and treatment) during the loan deferment period for each cancer type identified; and (5) identify measures that would be used to track annual progress in meeting the proposed goals in the three areas for each cancer type identified.

3. Domain 3: Unique Research Resources or an Affiliation With an Entity That Has Unique Research Resources

We are proposing that the qualifying hospital would describe in its plan how it would establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources and what those unique resources are.

C. Proposed Plan Criteria

1. Targeted Population

For targeting multiple Indian tribes, we are proposing that qualifying hospitals refer to the notice on ''Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs.'' The most recent notice was published in the **Federal Register** on December 5, 2003 (68 FR 68180). Qualifying hospitals would use this list when designating the target population for outreach programs servicing multiple Indian tribes since these are the Indian tribes that have unique legal status under Federal law.

For other target populations, we are not proposing how the qualifying hospital should determine or designate the population as long as it encompasses a substantial majority of the residents of a State or region, including residents of rural areas that it services. We believe that the qualifying hospital is in the best position to designate the targeted populations for their outreach programs to the substantial majority of residents and to rural areas. We believe that allowing the qualifying hospital to designate its populations provides flexibility over the life of the loan deferment period as its populations change due to results from its outreach programs, treatment services, or other reasons. However, we are proposing that the qualifying hospital provide sufficient detail in its initial plan to clearly describe how it designated its targeted populations and that the populations designated should be in accordance with the provisions of the statute. The qualifying hospital should include in the plan such details as demographic information for the targeted population generally and some initial estimates of relevant rates of diagnosis of and death from cancers prevalent in its population(s).

2. Identification of the Cancer Types

In this proposed rule, we are not proposing specific cancers (or the number of cancer types) that the qualifying hospital must focus on in its outreach programs. Again, we believe that the qualifying hospital is in the best position to determine the types of cancer to target in its outreach programs and that allowing the qualifying hospital to determine the cancer types provides flexibility over the life of the loan deferment period as the population changes or cancer prevention and treatment services improve. However, we are proposing that the qualifying hospital provides sufficient detail in its initial plan to clearly describe how it would identify the cancer types that it is targeting. The reasons for selecting specific cancers may include such things as high prevalence or incidence, high mortality or morbidity, easily treatable, available screening techniques, and easily diagnosed. The four most common cancers—prostate, breast, lung, and colon/rectum—accounted for more than half of all new cases of cancer in 1998 and qualifying hospitals may wish to target these cancers in their outreach programs. [National Cancer Policy Board (IOM). Ensuring Quality Cancer Care.

Washington DC: National Academy Press, 1999]

3. Intervention Approaches

In this propose rule, we are not mandating specific intervention approaches that the qualifying hospital must conduct in its outreach programs. We believe that the qualifying hospital is in the best position to determine the types of interventions to implement based on its target population and the types of cancers included in its outreach programs. We believe that allowing the qualifying hospital to determine its specific interventions provides flexibility to the qualifying hospital to try different approaches over the life of the loan deferment period. However, we are proposing that the qualifying hospital provide sufficient detail in its initial plan and subsequent progress reports to clearly describe the approaches it will be conducting or implementing, including the reasons why the intervention approaches were selected and why they may make a difference in improving cancer care for the targeted population.

4. Goals for Improvement

We are proposing in § 505.15 that the qualifying hospital include in its plan, improvement goals for the prevention, early diagnosis, and treatment, for each cancer type identified in its outreach programs. The qualifying hospital must work towards these goals during the loan deferment period. We believe that it is important to establish goals for improving performance over the loan deferment period as one way to document the potential impact of its outreach programs on improvement in the care provided to the targeted populations. This would help the qualifying hospital determine if its outreach programs are getting the desired results.

As previously indicated, we are not proposing specific goals for the qualifying hospital to achieve. However, we are proposing that the qualifying hospital must determine its own improvement goals for each cancer type (that is for the prevention, early diagnosis, and treatment). We believe that it is important for the qualifying hospital to determine its own goals because it is in the best position to know or understand the various factors or barriers in its population (community) that may influence the achievement of the goals and work towards overcoming them. For example, if the qualifying hospital selects breast cancer as one of the cancer types it would focus on for the designated population, the qualifying hospital may select a goal of decreasing the number of new initial breast cancer diagnosis or cases by 10 percent from the previous year (a prevention goal), or select a goal of increasing the number of mammograms performed by 10 percent from the previous year (an early diagnosis goal), or select a goal of increasing the number of patients who receive their first treatment after initial diagnosis within the time period specified by the appropriate clinical practice guidelines (a treatment goal). We understand that there are many factors to take into account when selecting goals, but we believe that it is important for the qualifying hospital to work towards established goals so that it can determine if its outreach programs are having the desired effect and changes to its outreach approaches can be made as needed.

5. Measures

We are proposing in § 505.17 that the qualifying hospital include in its initial plan at least one measure (for example, either an outcome measure or a process measure) used to track its progress in achieving the goals it has established for each area of prevention, early diagnosis, and treatment, for each cancer type identified in its plan. We are not proposing the specific measures that the qualifying hospital should track because we believe that the qualifying hospital is in the best position to determine the appropriate measures. Furthermore, we believe that it provides flexibility and allows the goals to be revised because of various factors or barriers (for example, community) that may influence the achievement of the goal to have changed. For example, if the qualifying hospital identifies lung cancer as one of the cancer types it would focus on for the designated population, the qualifying hospital may select the percent of patients enrolled in smoking cessation sessions and who quit smoking for 1 year or more as a measure to track its prevention goal. The qualifying hospital may select the percent of patients at high risk for developing lung cancer who receive a screening test as a measure to track its early diagnosis goal, and it may select the percent of patients who were initially diagnosed with lung cancer and received the appropriate treatment timely to track its treatment goal. The goal that is selected should drive what measure is selected for tracking the goal, such as goals for early diagnosis and treatment.

6. Unique Research Resources

We are proposing in § 505.15(b) that the qualifying hospital include in its plan a description of how it would establish or maintain existing unique research resources or how it would establish or maintain an existing affiliation with another entity that has unique research resources. Examples of unique research resources are a population database, a cancer biomedical informatics system, a surveillance system for observing or measuring cancer incidence, morbidity, survival, and/or mortality, an epidemiology study, an end results database, or a tumor registry. We are soliciting comments on other unique research resources that may be available.

D. Reporting Requirements for Meeting the Conditions for Loan Forgiveness (Proposed § 505.17)

[If you choose to comment on issues in this section, please include the caption ''Reporting Requirements'' at the beginning of your comments.]

We are proposing that the qualifying hospital must submit annual progress reports to CMS describing its progress in achieving its plan or any changes to the initial plan. We would review the annual progress reports and provide feedback to the qualifying hospital, so that it is aware of its loan forgiveness status during the loan deferment period.

Annual progress reports from the qualifying hospital would allow us to monitor the qualifying hospitals performance in meeting the conditions for loan forgiveness during the loan deferment period. We intend to monitor the qualifying hospitals' performance during the entire loan deferment period to ensure that these qualifying hospitals meet the conditions for loan forgiveness. We would require qualifying hospitals to submit the final progress report to us 6 months before the end of the loan deferment period. At that time, we would determine whether the qualifying hospital has met the loan forgiveness conditions. We are proposing this timeframe since determinations of loan forgiveness must be made at the end of 5 years.

E. Approval or Denial of Loan Forgiveness (Proposed § 505.19)

[If you choose to comment on issues in this section, please include the caption ''Approval or Denial of loan forgiveness'' at the beginning of your comments.]

We are proposing that if a qualifying hospital meets the conditions, plan criteria, and reporting requirements for loan forgiveness specified in § 505.13, § 505.15, and § 505.17, the loan would be forgiven. Therefore, we would send

written notification for the loan forgiveness approval to the loan recipient 90 days before the end of the loan deferment period. We are proposing that if the loan recipient does not meet the conditions, plan criteria, or reporting requirements for the loan forgiveness specified in § 505.13, § 505.15, and § 505.17, we would send written notification for the denial of the loan forgiveness.

III. Collection of Information Requirements

The collection of information requirements at 5 CFR part 1320 are applicable to requirements affecting 10 or more entities. While this proposed rule contains information collection requirements, because we believe that these requirements would affect less than 10 entities, we believe that these collection requirements are exempt from OMB for review and approval, as specified at 5 CFR 1320.3(c)(4). Consequently, this proposed rule need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble. Thus, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is not a major rule because it does not have an effect of more than $100 million in any 1 year.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of the RFA, all hospitals are considered small businesses according to the Small Business Administration's latest size standards with total revenues of $26 million or less in any 1 year (for further information, see the Small Business Administration's regulation at 65 FR 69432, November 17, 2000). Individuals and States are not included in the definition of a small entity. This proposed rule affects qualifying hospitals as defined by section 1897 of the Act that have been selected to receive funds under the loan program. We believe a total of 61 facilities meet the definition of qualifying hospitals under section 1897 of the Act (that is, 60 NCI cancer centers and 1 State legislature designated cancer institute, but only a few hospitals would actually be selected to receive funds under the loan program and be eligible for loan forgiveness).

In addition, section 1102(b) of the Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. None of the eligible facilities are small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule who mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, nor would it result in expenditures by the private sector of $120 million in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Section 1897 of the Act directly specifies that no provisions under the Program implemented by this proposed rule would relieve an obligation of State and local permits or limit or otherwise supersede any State or local law.

B. Anticipated Effects

1. Effects on Hospitals

The provisions of this proposed rule are limited to qualifying hospitals that have received funds under the loan program and are eligible for loan forgiveness. Only 61 facilities would meet the definition of qualified hospitals as required by section 1897 of the Act. Since the capital costs of projects which the loan program is designed to pay for are likely to be substantial and expensive, we expect only a small percentage of the 61 eligible facilities would actually be granted loans under this provision before the funds are exhausted and therefore be eligible for loan forgiveness. For the few qualifying hospitals that would receive funds under the loan program, we expect they would use the money on projects that are ''designed to improve the healthcare infrastructure of the hospital including construction, renovation, or other capital improvements'' and which would result in better facilities in which to provide cancer care to our beneficiaries. To qualify for loan forgiveness, the qualifying hospitals must meet the conditions specified in section 1897(f) of the Act, which we believe would positively impact the cancer care our beneficiaries receive. As well, the qualifying hospitals would realize a benefit when their loans are forgiven. However, we believe that the effect would be limited to those few qualifying hospitals that have received loan funds and are eligible for loan forgiveness. Thus, the provisions in this proposed rule would not have a significant economic impact on a substantial number of hospitals.

2. Effects on the Medicare and Medicaid Programs

The $142 million in available loan funds is appropriated for the loan program and not more than $2,000,000 may be used for the administration costs of the loan program.

C. Alternatives Considered

We considered no alternatives to the policies in this proposed rule since the statute authorizes the conditions under which the Secretary may forgive a loan provided under the Health Care Infrastructure Improvement Program.

D. Conclusion

For these reasons, we are not preparing further analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 505

Administrative practice and procedure, Health facilities, Loan programs, Infrastructure improvement program, Reporting and recordkeeping, and Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

PART 505—THE ESTABLISHMENT OF THE HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

1. The authority citation for part 505 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C 1302 and 1395hh).

2. In 505.3 is amended by republishing the introductory text and adding the following definitions in alphabetical order to read as follows:

§ 505.3 Definitions

For purposes of this subpart, the following definitions apply:

* * * * *

Outreach programs mean formal cancer programs for teaching, diagnostic screening, therapy or treatment, prevention, or interventions to enhance the health and knowledge of their designated population(s).

* * * * *

Unique research resources means resources that are used for the purpose of discovering or testing options related to the causes, prevention, and treatment of cancer.

3. A new Subpart B is added to read as follows:

Subpart B—Forgiveness of Indebtedness

Secs.

Subpart B—Forgiveness of Indebtedness

§ 505.13 Conditions for loan forgiveness.

The Secretary may forgive a loan provided under this part if the qualifying hospital meets the following conditions:

(a) Must be selected to participate in the loan program specified in § 505.5(c) of this part.

(b) Has established the following:

(1) An outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

(2) An outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and

(3) Unique research resources (such as population databases) or an affiliation with an entity that has unique research resources.

(c) Submits to CMS within the timeframe specified by the Secretary a—

(1) Written request for loan forgiveness; and

(2) Loan forgiveness plan that meets the criteria specified in § 505.15 of this subpart.

§ 505.15 Plan criteria for meeting the conditions for loan forgiveness.

The qualifying hospital requesting loan forgiveness must submit to CMS a plan specifying how it will develop, implement, or maintain an existing outreach program for cancer prevention, early diagnosis, and treatment for a substantial majority of the residents of a State or region, including residents of rural areas and for multiple Indian Tribes and specifying how the qualifying hospital will establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources.

(a) *Outreach programs.* The initial plan must specify how the hospital will establish or develop, implement, or maintain existing outreach programs. The plan must—

(1) Address cancer prevention for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for decreasing the targeted cancer rates during the loan deferment program; and

(2) Address early diagnosis of cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving early diagnosis rates for the targeted cancer(s) during the loan deferment period;

(3) Address cancer treatment for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving cancer treatment rates for the targeted cancer(s) during the loan deferment; and

(4) Identify the measures that will be used to determine the qualifying hospital's annual progress in meeting the initial goals specified in paragraphs (a)(1) through (a)(3) of this section.

(b) *Unique research resources.* The plan must specify how the qualifying hospital will establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources.

§ 505.17 Reporting requirements for meeting the conditions for loan forgiveness.

(a) *Annual reporting requirements.* On an annual basis, the qualifying hospital must submit a report to CMS that updates the plan specified in § 505.15 of this subpart by—

(1) Describing the qualifying hospital's progress in meeting its initial plan goals;

(2) Describing any changes to the qualifying hospital's initial plan goals; and

(3) Including at least one measure used to track the qualifying hospital's progress in meeting its plan goals.

(b) *Review of annual reports.* CMS will review each qualifying hospital's annual report to provide the hospital with feedback regarding its loan forgiveness status.

(c) *Final reporting requirements.* A qualifying hospital must submit its final written report to CMS 6 months before the end of the loan deferment period specified in § 505.7(b) of this part.

§ 505.19 Approval or denial of loan forgiveness.

(a) *Approval of loan forgiveness.* If a qualifying hospital has met the conditions, plan criteria, and reporting requirements for loan forgiveness specified in § 505.13, § 505.15, and § 505.17 of this part, CMS will send a written notification of approval for loan

forgiveness to the qualifying hospital 90 days before the end of the loan deferment period defined in § 505.7(b) of this part.

(b) *Denial of loan forgiveness.* If a qualifying hospital has not met the conditions, plan criteria, or reporting requirements for loan forgiveness specified in § 505.13, § 505.15, or § 505.17 of this part, CMS will send a written notification of denial for loan forgiveness to the qualifying hospital.

Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 28, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 3, 2005.

Michael O. Leavitt,

Secretary.

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