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42 CFR Part 505

Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care; Forgiveness of Indebtedness; Interim Final Rule and Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 505

[CMS–1287–IFC]

RIN 0938–AO03

Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period sets forth the criteria for implementing a loan program for qualifying hospitals engaged in research in the causes, prevention, and treatment of cancer as specified in section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Specifically, this rule establishes a loan application process by which qualifying hospitals including specified entities may apply for a loan for the capital costs of health care infrastructure improvement projects.

DATES: *Effective Date:* This interim final rule with comment period is effective November 29, 2005.

Comment date: 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.

In commenting, please refer to file code CMS–1287–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Deadline for submission of loan requests: To be assured consideration, applications must be received at the appropriate address from November 29, 2005 through 5 p.m. on December 29, 2005.

ADDRESSES: *Comments:* 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–1287–IFC, 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.

Applications: Applications must be submitted to the following address: Centers for Medicare and Medicaid Services, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, Attention: Loan for Cancer Hospitals, Mail Stop C4–08–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: Tzvi Hefter, (410) 786–4487.

SUPPLEMENTARY INFORMATION:

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. 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 eligible projects.

Section 1897(c) of the Act 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 for 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 before 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 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.

Furthermore, before 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 Interim Final Rule With Comment Period

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 provides that criteria be established for—(1) selecting among qualifying hospitals that apply to participate in the loan program; and (2) forgiving indebtedness. This interim final rule with comment period establishes the loan program and the selection criteria for qualifying hospitals to participate in the loan program. We will publish a separate rule making document to describe the criteria for loan forgiveness.

A. Overview of the Loan Program

The statute provides specific definitions for a qualifying hospital and entity. However, in addition to being a ''hospital'' as defined in section 1861(e) of the Act or an ''entity'' as defined in section 1897(c)(3) of the Act, the applicant must meet the criteria described in section 1897(c)(2) of the Act in order to be considered a qualifying hospital.

To be designated as a cancer center for the NCI of the National Institutes of Health (NIH), the hospital must have been awarded a P30 Cancer Center Support Grant (CCSG) from NCI to fund the scientific infrastructure of the cancer center, see *http://www.cancer.gov/cancercenters/description.html.*

NCI designates two types of cancer centers: cancer centers, and comprehensive cancer centers. NCI describes ''cancer centers'' as those that have a scientific agenda that is primarily focused on basic science, population-based research or clinical research, or any two of the three components.

NCI describes ''comprehensive cancer centers'' as those that integrate research activities across three major areas: Laboratory, clinical, and population-based research. Hospitals that have been awarded a CCSG and are designated by NCI as either a cancer center or a comprehensive cancer center before December 8, 2003, will be considered qualifying hospitals. We chose the December 8, 2003 date for the NCI CCSG designation because it is the date of enactment of the MMA and consistent with the statutory date for State legislature designation of the official cancer institute of the State.

To be designated as the official cancer institute of the State, the entity must be designated by the State legislature as ''the official cancer institute of the State.'' Section 1897 of the Act specifies that designation by the State legislature must have occurred before December 8, 2003.

In this rule, we have added Subchapter H—Health Care Infrastructure Improvement Program to comply with section 1897 of the Act. Specifically, we have added part 505—''Establishment of the Health Care Infrastructure Improvement Program.'' We have added subpart A—Loan Criteria. Section 505.1 sets forth the ''Basis and Scope'' of part 505 which implements section 1016 of the MMA which amends Title XVIII of the Act to add section 1897. Section 1897 of the Act, as amended by section 6045 of the Tsunami Relief Act of 2005, authorizes the Secretary to establish a loan program by which qualifying hospitals may apply for a loan for the capital costs of the health care infrastructure improvement projects.

In § 505.3, for purposes of subpart A, we have set forth the following definitions:

• *Eligible project* means the project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

• *Entity* is an entity described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of the code. An entity also 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, education, and outreach for cancer in the same facility.

• *Qualifying hospital* means a hospital as defined at section 1861(e) of the Act (42 U.S.C. 1395x(e)) or an entity (as defined in this section) that is—

(1) Engaged in research in the causes, prevention, and treatment of cancer; and is either

(2) Designated as a cancer center for the National Cancer Institute; or

(3) Designated by the State legislature as the official cancer institute of the State before December 8, 2003.

B. Qualifying Hospital Criteria for the Loan Program

The statute provides the following two sets of criteria for establishing the loan program: (1) Selecting among qualifying hospitals; and (2) forgiving indebtedness (that is, deciding if the loan funds may be forgiven). The statute also specifies conditions under which a loan may be forgiven. These conditions are based upon the qualifying hospital's establishment of the following:

• 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;

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

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

Since the statute outlines specific criteria in which to forgive loans, we believe that it is consistent with the Congressional intent to give priority to qualifying hospitals that meet at least some of the statutory conditions for loan forgiveness when selecting qualifying hospitals for the loan program.

Although the statute does not require that these provisions be adopted as criteria for receiving funds under the loan program, these criteria are specified in statute for qualifying for loan forgiveness. Therefore, we recognize that it is not possible to forgive the qualifying hospital's debt if it had not initially been selected to receive funds under the loan program.

As previously stated, we will publish a separate rule-making document on the forgiveness of indebtedness. We are seeking specific comment on what additional criteria we should establish for any qualifying hospitals that do not meet these initial criteria, in the event that after granting loans to the initial applicants there are residual funds up to the $140 million maximum available for loan funds.

In § 505.5(a), we set forth the ''qualifying criteria'' requirements. To qualify for the loan program, the applicant must—

• Meet the definition of a qualifying hospital as set forth in § 505.3 of this part; and

• Request a loan for the capital costs of an eligible project as defined in § 505.3 of this part. The capital costs for which a qualifying hospital may obtain a loan are limited to the reasonable costs incurred by the hospital, and capitalized

on the Medicare cost report, for any facility or item of equipment that it has acquired the possession or use of at the time the loan funding is awarded.

C. Selection Criteria

In § 505.5(b), we set forth the ''selection criteria'' requirements. In selecting loan recipients, we will prioritize qualifying hospitals that meet the following criteria:

- The hospital is located in a State which based on population density is defined as a rural State. A rural State is one of ten States with the lowest population density. The ten States are prioritized beginning with the State with the lowest population density. Population density is determined based on the most recent available U.S. Census Bureau data.
- The hospital is located in a State with presence of multiple Indian tribes in the State. After prioritizing based on paragraph (b)(1), States are further prioritized based on the States with the most Indian tribes. The number of Indian tribes in the State is based on the most recent data available published in ''Indian Entities Recognized and Eligible to Receive Services from the United State Bureau of Indian Affairs'' (68 FR 68180) published on December 5, 2003.

1. Rural States

We recognize that conducting outreach to Indian tribes in sparsely populated, rural areas presents additional barriers and challenges. According to the Health Resources and Services Administration's (HRSA) History of the Rural Health Care Services Outreach Grant Program (2004), the rural population of the U.S. differs significantly from the urban population in such parameters as age, income, education, and health status. The HRSA report can be found at *http://www.ruralhealth.hrsa.gov/funding/outreachhistory.asp*. The HRSA report also states that generally, non-metropolitan populations have higher rates of poverty and unemployment and have fewer years of education than their metropolitan counterparts. Also according to the HRSA report, rural residents also experience poorer health status. Furthermore, the same report maintains that there are higher rates of chronic disease, infant mortality, accidental injuries related to farming activities, occupational hazards, and trauma mortality in rural areas as compared to metropolitan areas. In accordance with the HRSA report, lack of access to health care in rural communities compounds the effect of these health problems and that long distances between rural and urban communities and inadequate public transportation systems for rural areas further worsen these conditions.

Additionally, cancer care requires a sophisticated set of surgical and medical resources; however currently those resources are more commonly found in large urban settings. Finally, the HRSA report found that greater proportions of rural cancer patients are diagnosed at later stages than urban patients and are less likely than urban patients to receive state-of-the-art cancer treatments.

These factors illustrate some of the difficulties faced when trying to develop new and innovative cancer care outreach systems in rural communities.

Given the inherent barriers in conducting outreach in rural areas and the statutory priority placed on a qualifying hospital establishing an outreach program that services a substantial majority of the residents of a State, including residents of rural areas, we are prioritizing applicant entities located in rural States. One way to identify States that are rural is based on population density. Using population density as a measure of rural status is consistent with another section of the statute, which directs the establishment of a rural community hospital demonstration in States with low population densities (see section 410A of the MMA).

Section 410A of the MMA established a Rural Community Hospital Demonstration Program where the Secretary was given the authority to determine rural areas and select States with low population densities. In implementing section 410A of the statute, the Secretary determined the ten States with the lowest population density. Using Census Data released in 2004, the ten States with the lowest population density are: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming.

Since the loan forgiveness criteria in section 1016 of the MMA also focus on rural populations (that is, establishing outreach programs that provide services to residents of rural areas) and in order to be consistent, for purposes of implementing section 1016 of the MMA, we have chosen to use the same criteria we used to implement section 410A of the MMA to determine States with low population density. Therefore, we are requiring that qualifying hospitals be located in 1 of the 10 States with the lowest population density in order to receive funding under section 1897 of the Act.

2. Indian Tribes

The statute places a priority for loan forgiveness on qualifying hospitals that conduct outreach to multiple Indian tribes. Therefore, we believe it is important that funds under section 1897 of the Act be directed to qualifying hospitals in States that have a significant presence of Indian tribes. To identify States that have a significant presence of Indian tribes, we looked to the list of ''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) by the Department of the Interior, Bureau of Indian Affairs.

The statute places a top priority for loan forgiveness on hospitals that are conducting outreach programs, specifically, on outreach programs that provide services to multiple Indian tribes. Since the Congress provided special recognition in the loan forgiveness criteria to qualifying hospitals providing outreach services to multiple Indian tribes, we believe it is appropriate to focus on this same criteria in prioritizing which qualifying hospitals should be granted a loan. Therefore, we have based the second loan selection criterion on the presence of multiple Indian tribes, that is, that the qualifying hospital be located in a State with a large number of Indian tribes. We do not believe, in light of our understanding of the congressional intent, that it would be appropriate to initially provide for loans under section 1897 of the Act to qualifying hospitals in States which do not have a significant Indian tribe presence.

Therefore, in light of this priority on hospitals providing outreach to Indian tribes, the second criterion we are using to further rank qualifying hospitals is based on the number of Indian tribes within a State. Qualifying hospitals located in 1 of the 10 States with the lowest population densities (States that meet the first criterion) will be ranked subsequently according to the number of Indian tribes, in which the States with the most Indian tribes are given top priority. We believe hospitals and entities located in States with many Indian tribes, spread over a large, sparsely populated area, should be given first priority for loans under section 1897 of the Act, given the focus in the statute on rural populations and Indian tribes.

Table 1 below, shows the 10 least densely populated States, and ranks them according to the number of Indian tribes.

TABLE 1.—LEAST DENSELY POPULATED STATES

Rank for purposes of Section 1016 of the MMA	State	Number of Indian tribes	Population density—average population per square mile
1	Alaska	229	1.2
2	New Mexico	23	15.7
3	Nevada	19	21.3
4	South Dakota	9	10.2
5	Montana	7	6.4
6	Utah	7	29.1
7	Nebraska	6	22.7
8	North Dakota	4	9.2
9	Idaho	4	16.8
10	Wyoming	2	5.2

Source: ''Indian Entities Recognized and Eligible to Receive Services from the United State Bureau of Indian Affairs.'' The most recent notice was published in the FEDERAL REGISTER on December 5, 2003 (68 FR 68180).

U.S. Census Bureau, Population Division, Population Estimates Program, Population Density for States and Puerto Rico, July 1, 2004, *http://www.census.gov/popest/gallery/maps/popdens_2004.html*.

D. Application and Selection Criteria (§ 505.11)

1. Application Requirements

Qualifying hospitals interested in applying for the loan program must complete the loan application form which is available at *http://www.cms.hhs.gov/providers/hipps*. The qualifying hospital must provide all appropriate supporting documentation for each answer made on the loan application. The appropriate official (that is, a Chief Financial Officer, Chief Executive Officer or equivalent) of the qualifying hospital must provide signatures for each place indicated on the application. In accordance with the foregoing discussion, we believe qualifying hospitals located in States with multiple (or a significant number) of Indian tribes and low population density, should be given first priority for loans under section 1897 of the Act.

2. Submission of Application

We will begin to accept applications on September 30, 2005. All applications must be received by CMS no later than 5 p.m. on December 29, 2005. The request must be mailed or delivered by courier service. Facsimile (fax) or other electronic means are not acceptable. The request must be typed or clearly printed in ink. Qualifying hospitals must mail or deliver an original copy of their loan application to the following address: Centers for Medicare & Medicaid Services, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, Attention: Loan for Cancer Hospitals Mail Stop C4–08–06 7500 Security Boulevard Baltimore, Maryland 21244–1850.

Applicants may want to send their application by a delivery method that guarantees a signed receipt, which indicates delivery and date of delivery of their loan request. The address listed above is applicable for both United States mail and courier service delivery.

3. Evaluation Process

When we receive applications from qualifying hospitals, we will first evaluate the applicants to determine whether they meet the minimum qualifications as specified in section 1897 of the Act (that is, they are NCI designated cancer centers or designated as the official cancer institute of the State). We will then rank applicant entities based on the criteria as specified in § 505.5. We will continue to evaluate the request for funds under the loan program from any applicants in the highest ranking State, and subsequently move to the next highest ranking State, until the funds allocated under the loan program are exhausted.

If there are multiple qualified applicants from the State with requests for funds under the loan program that exceed the amount of funds remaining, we will pro-rate all loan requests of entities in that State to determine the loan amount for each applicant.

4. Capital Costs Criteria

Section 1897 of the Act provides for making loans to a qualified hospital to pay for the capital costs of projects. Projects are defined as those designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements. Therefore, the capital costs for which a qualifying hospital may obtain funds under the loan program will be based on the reasonable costs incurred by the hospital. In addition, the capital costs are to be appropriately capitalized on the Medicare cost report, for any facility or item of equipment that it has acquired the possession or use of at the time of application for the loan program. In determining the reasonableness of the amount of the loan for any particular facility or item for purposes of the loan program, the hospital and CMS will follow Medicare reasonable cost principles as specified in Medicare regulations and program operating instructions. Payment based on reasonable cost principles is a long-standing and established methodology used by Medicare and we believe it is appropriate to apply it to the loan program.

Accordingly, a qualifying hospital that has acquired or built a facility and/or has acquired equipment as an eligible project defined at § 505.3 and the acquisition costs of the asset(s) are appropriately reported on its Medicare cost report following Medicare reasonable cost principles, could apply for a loan not to exceed the net book value of the asset(s) as of the date of its application to CMS for the loan program. Since CMS has been directed to implement section 1897 of the Act, we believe that it is appropriate to apply the standard Medicare interest rate specified in 45 CFR 30.13(a), established by the Secretary of the Treasury, and published quarterly in the **Federal Register**, which we use for our Medicare program, to the loan program.

Alternatively, if a qualifying hospital had not acquired the possession or use of the asset(s) by the date of the application for the funds available under the loan program, the reasonable cost of the asset(s) could nevertheless be the basis for the hospital to apply for funds available under the loan program if the hospital has entered into a contractual obligation via a binding written agreement before December 8, 2003 (the date of enactment of the

MMA) in order to ensure that the funds are being used in accordance with the program.

The amount of the loan cannot exceed the cost of the asset as of the date the application is due to CMS September 30, 2005 based on the cost in the binding written agreement and following Medicare reasonable cost principles.

E. Terms of the Loan Program

In § 505.7, we set forth the ''terms and conditions'' of the loan program.

In order to be awarded funds under the loan program, a participating entity must meet the criteria of a qualified hospital or entity as specified in § 505.3.

1. Loan Obligation (§ 505.7(a))

An authorized official of each qualifying hospital must execute a promissory note, loan agreement, or any other approved form that we may designate, to ensure compliance with the terms of the loan program.

2. Schedule of Loan (§ 505.7(b))

Each loan recipient will receive a lump sum distribution for which payment of principal and interest is deferred for 60 months beginning with the day we notify the qualifying hospital of award notification. The loan repayment period is 20 years. However, the loan recipient must agree to furnish to us cancer care data during the deferment period.

3. Bankruptcy Protection (§ 505.7(c))

In the event a loan recipient should file for bankruptcy protection in a court of competent jurisdiction or should otherwise evidence insolvency, we may terminate the deferment and require immediate payment of the loan. If a loan recipient should file for bankruptcy protection in a court of competent jurisdiction or should otherwise evidence insolvency after the deferment period we will require immediate repayment of the outstanding principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

4. Loan Forgiveness (§ 505.7(d))

As previously mentioned, we are publishing a separate rule making document regarding the forgiveness of indebtedness in which we will propose criteria as specified in the statute.

5. Default (§ 505.7(e))

Additionally, if a loan recipient fails to make any payment in repayment of a loan under the loan program within 10 days of its due date, the loan recipient may be considered in default on the loan. Under the Federal Debt Collection Act, upon default, all principal and interest become due immediately, and we reserve the right to collect on any remaining principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

F. Loan Repayment (§ 505.7(f))

The loan recipient agrees to make payments every month for 20 years until the loan, including interest, is repaid. For qualifying hospitals that are ineligible for loan forgiveness, payments are due starting on the first day of the next month following the deferment period. Payments will be made monthly until all of the principal and interest owed are paid in full. Interest will be charged on the unpaid principal until the full amount of principal has been paid. A loan recipient will pay interest at a yearly rate based upon the rate as fixed by the Secretary of the Treasury which is published quarterly in the **Federal Register** as specified in 45 CFR 30.13(a). Payments must be mailed to: CMS/Division of Accounting Operations, P.O. Box 7520, Baltimore, MD 21207–0520.

G. Payments

1. Interest Rate and Monthly Payment Changes (§ 505.7(g))

The regulations in 42 CFR part 405 subpart C provide authority for us to collect interest on certain payments. Therefore, to the extent that payments are due, we are establishing that interest charges and payments be made consistent with § 405.378.

2. Loan Recipient's Right To Prepay (§ 505.7(h))

A loan recipient has the right to make payments of principal at any time before they are due. A payment of principal only is known as a ''prepayment.'' A loan recipient may make full prepayment or partial prepayment without paying any prepayment charge. When a prepayment is made, the qualifying hospital must provide us with written notice.

H. State and Local Permits (§ 505.9)

In § 505.9, we set forth the ''State and local permit'' requirements. Consistent with section 1897 of the Act, the entity must agree to the following terms and conditions: The provision of a loan under section 1897 shall not—

- Relieve the hospital of any obligation to obtain any required State or local permit or approval with respect to the project;
- Limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project; or
- Otherwise supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

III. Response to Comments

Because of the large number of public comments 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, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the effective date of the rule. This procedure can be waived, however, when an agency finds good cause that a notice and comment procedure is impracticable, unnecessary or contrary to the public interest. We find good cause to implement this rule as an interim final rule because the delay involved in the prior notice and comment procedure for the loan program for the infrastructure for cancer centers would be impracticable and contrary to the public interest.

The Congress enacted section 1897 of the Act to provide a loan program for a qualifying hospital to improve the health care infrastructure of the hospital. The program is designed to enable a number of cancer hospitals to expand or improve their healthcare infrastructure, develop enhanced capacity and research resources, and serve the medical needs of their populations. We believe that it is not in the public interest to delay the loan program and prevent the affected parties from having access to such services.

The Congress provided $142,000,000 for the loan program effective July 1, 2004 through September 30, 2008, and not more than $2,000,000 may be used for the administration of the loan program for each of the fiscal years (that is, 2004 through 2008).

These legislative changes demonstrate that the Congress has concerns about the improvement of the cancer-related health care hospital infrastructure in the United States. As specified in section 1897(c)(2) of the Act, in order to receive funds under the loan program, an applicant entity is required to—(1) be engaged in research into the causes, prevention, and treatment of cancer; (2) be designated as a cancer center for the

NCI, or be designated by the State legislature as the official cancer institute of the State before December 8, 2003. Delay in issuing this interim final rule with comment period could hinder our programmatic objective of improving cancer care and outreach, particularly with respect to the residents in rural areas, and Indian tribes. For example, this interim final rule with comment period provides funding to hospitals in rural areas that engage in research in the causes, prevention, and treatment of cancer and that establish an outreach program for cancer prevention, early diagnosis, and treatment. Beneficiary access to quality cancer care in underserved or rural areas is a critical programmatic objective. It is not in the public interest to delay finalizing this loan program which is designed to serve this purpose.

The Congress further indicated that the selection criteria for making loans consider the extent of medical benefit gained from projects to expand or improve the health care infrastructure for which this loan program is intended. The funds made available to improve that infrastructure are only available for a time-limited period (ending September 30, 2008) and nearly 1 year has passed since those funds were first made available. It would be impracticable and contrary to the public interest to issue a proposed rule and further delay access to these time-limited funds.

In accordance with the foregoing, we believe that it would be impracticable and contrary to the public interest to delay implementation of the loan program pending the process of publishing both a proposed rule and a final rule. Publishing these provisions in an interim final rule with comment period will give the public an opportunity to submit comments. Publication of this interim final rule with comment period will serve the public interest by ensuring that providers have access to funds, and that beneficiaries, Indian tribes, and residents of rural areas have access to improved cancer outreach services, as expeditiously as possible, consistent with Congressional intent. Therefore, in order to establish the loan application process and selection criteria to award the funds of the time-limited loan program, we find good cause to waive proposed rulemaking for the revised requirements set forth under the Administrative Procedure Act (5 U.S.C. 553(b))and to issue these regulations in final. However, we are providing a 60 day period for public comment, as indicated at the beginning of this rule.

V. Collection of Information Requirements

The collection of information requirements at 5 CFR 1320 are applicable to requirements affecting 10 or more entities. While this regulation contains information collection requirements, because we believe that these requirements will 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 rule does not need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact

A. Overall Impact

We have examined the impacts of this 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 interim final rule with comment period is a major rule in which $142 million is appropriated to carry out the Health Care Infrastructure Improvement Program.

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 interim final rule with comment period affects qualifying hospitals as defined by section 1897 as—(1) a hospital or entity as defined in § 505.3 that is engaged in research in the causes, prevention, and treatment of cancer; and (2) designated as a cancer center for 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 before December 8, 2003. We believe a total of 61 facilities meet the definition of qualifying hospitals as specified in § 505.3 (that is, 60 NCI cancer centers and 1 State legislature designated cancer institute).

In addition, section 1102(b) of the Act requires us 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 604 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 61 eligible facilities that we have identified are 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 whose 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 interim final rule with comment period does not mandate any requirements for State, local, or tribal governments, nor will 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. As specified in section 1897 of the Act, no provisions under the loan program will relieve an obligation of State, local permits or limit or otherwise supersede any State or local law.

B. Anticipated Effects

1. Effects on Hospitals

The provisions of this interim final rule with comment period are limited to qualifying hospitals. Only 61 facilities

meet the definition of qualified hospitals as specified in § 505.3. 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 will actually be granted loans under this provision before the funds are exhausted. For the few qualifying hospitals that will receive funds under the loan program, we expect they will 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. However, we believe that the effect will be limited to those few qualifying hospitals that will receive loan funds. Thus, the provisions in this IFC will not have a significant economic impact on a substantial number of hospitals.

2. Effects on the Medicare and Medicaid programs

This interim final rule with comment period will have little impact on the Medicare trust fund. The Congress provided $142,000,000 for the loan program effective July 1, 2004 through September 30, 2008, and not more than $2,000,000 may be used for the administration of the loan program for each of the fiscal years (that is, 2004 through 2008).

C. Alternatives Considered

We considered no alternatives to the policies in this interim final rule with comment period since the statute authorizes the establishment of these policies.

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 will 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 amends 42 CFR chapter IV by adding a new subchapter H (consisting of a new part 505) to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

PART 505—ESTABLISHMENT OF THE HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

Subpart A—Loan Criteria

Secs.

505.1 Basis and scope.
505.3 Definitions.
505.5 Loan criteria.
505.7 Terms of the loan.
505.9 State and local permits.
505.11 Loan application requirements and procedures.

Subpart B—[Reserved]

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

Subpart A—Loan Criteria

§ 505.1 Basis and scope.

This part implements section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) which amends section 1897 of the Act. Section 1897 of the Act as amended by section 6045 of the Tsunami Relief Act of 2005 authorizes the Secretary to establish a loan program by which qualifying hospitals may apply for a loan for the capital costs of the health care infrastructure improvement projects. Section 1897 of the Act appropriates $142,000,000 for the loan program including program administration. The funds are available beginning July 1, 2004 through September 30, 2008. This part sets forth the criteria that CMS uses to select among qualifying hospitals.

§ 505.3 Definitions.

For purposes of this subpart, the following definitions apply:

Eligible project means the project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

Entity is an entity described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of the code. An entity must also have 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 laboratory research, education, and outreach for cancer in the same facility.

Qualifying hospital means a hospital as defined at section 1861(e) of the Act (42 U.S,C. 1395x(e)) or an entity (as defined in this section) that is engaged in research in the causes, prevention, and treatment of cancer; and is either designated as a cancer center for the National Cancer Institute; or designated by the State legislature as the official cancer institute of the State before December 8, 2003.

§ 505.5 Loan criteria.

(a) *Qualifying criteria.* To qualify for the loan program, the applicant must meet the following conditions:

(1) Meet the definition of a ''qualifying hospital'' as set forth in § 505.3 of this part.

(2) Request a loan for the capital costs of an ''eligible project'' as defined in § 505.3 of this part. The capital costs for which a qualifying hospital may obtain a loan are limited to the reasonable costs incurred by the hospital, and capitalized on the Medicare cost report, for any facility or item of equipment that it has acquired the possession or use of at the time the loan funding is awarded.

(b) *Selection criteria.* In selecting loan recipients, CMS prioritizes qualifying hospitals that meet the following criteria:

(1) The hospital is located in a State that, based on population density, is defined as a rural State. A rural State is one of ten States with the lowest population density. An applicant entity is required to be located in one of these ten States. The ten States are prioritized beginning with the State with the lowest population density. Population density is determined based on the most recent available U.S. Census Bureau data.

(2) The hospital is located in a State with multiple Indian tribes in the State. After prioritizing based on paragraph (b)(1) of this section, States are further prioritized based on the States with the most Indian tribes. The number of Indian tribes in a State is based on the most recent data available published in ''Indian Entities Recognized and Eligible to Receive Services from the United State Bureau of Indian Affairs.'' (68 FR 68180) published on December 5, 2003.

(c) CMS will send written notice to qualifying hospitals that have been selected to participate in the loan program under this part.

§ 505.7 Terms of the loan.

All loan recipients must agree to the following loan terms:

(a) *Loan obligation.* An authorized official of a qualifying hospital must execute a promissory note, loan agreement, or a form approved by CMS and accompanied by any other

documents CMS may designate. The loan recipient must provide required documentation in a timely manner.

(b) *Schedule of loan.* A loan recipient receives a lump sum distribution for which payment of principal and interest is deferred for 60 months beginning with the day of award notification from CMS. The loan repayment period is 20 years.

(c) *Bankruptcy protection.* In the event a loan recipient files for bankruptcy protection in a court of competent jurisdiction or otherwise proves to be insolvent, CMS may terminate the deferment period described in paragraph (b) of this section and require immediate payment of the loan. If a loan recipient should file for bankruptcy protection in a court of competent jurisdiction or should otherwise evidence insolvency after the deferment period we will require immediate repayment of the outstanding principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

(d) *Loan forgiveness.* CMS does not require a loan recipient to begin making payments of principal or interest at the end of the 60-month deferment period if it determines that the loan recipient meets the criteria for loan forgiveness under section 1897 of the Act, as determined by the Secretary.

(e) *Default.* If a loan recipient fails to make any payment in repayment of a loan under this subpart within 10 days of its due date, the loan recipient may be considered to have defaulted on the loan. Upon default, all principal and accrued interest become due immediately, and CMS may require immediate payment of any outstanding principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

(f) *Loan repayment.* The loan recipient must meet the following conditions:

(1) Make payments every month for 20 years until the loan, including interest payments, are paid in full.

(2) Pay interest on the unpaid principal until the full amount of principal has been paid.

(3) Pay interest at a yearly rate based upon the rate as fixed by the Secretary of the Treasury and set forth at 45 CFR 30.13(a).

(4) If a loan recipient fails to make any payment in repayment of a loan under this subpart within 10 days of its due date, that payment may be deducted from any Medicare payments otherwise due to the recipient.

(g) *Interest rate and monthly payment charges.* CMS calculates interest charges and payments consistent with § 405.378 of this chapter.

(h) *Loan recipient's right to prepay.* A loan recipient has the right to make payments of principal at any time before they are due. A loan recipient may make full prepayment or partial prepayment without paying any prepayment charge. If a prepayment is made, the loan recipient must provide written notice to CMS at CMS, Division of Accounting Operations, P.O. Box 75120, Baltimore, MD 21207–0520.

§ 505.9 State and local permits.

With respect to an eligible project, the provision of a loan under this part shall not—

(a) Relieve the recipient of the loan or any obligation to obtain any required State or local permit or approval with respect to the project.

(b) Limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project.

(c) Supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

§ 505.11 Loan application requirements and procedures.

(a) The loan application must be received by CMS no later than 5 p.m. e.d.t. on December 29, 2005.

(b) The requested information must be typed or clearly printed in ink and the loan recipient must mail or deliver an original copy of the loan to CMS. The loan application must contain the following information:

(1) Qualifying hospital's name and street address.

(2) Qualifying hospital's Medicare provider number.

(3) Name, title, and telephone number of a contact person submitting the application.

(4) Provide all appropriate supporting documentation for each answer made on the loan application.

Subpart B—[Reserved]

(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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