SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

PART 505—ESTABLISHMENT OF THE HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

Subpart A—Loan Criteria

Sec.

Subpart B—Forgiveness of Indebtedness

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

SOURCE: 70 FR 57374, Sept. 30, 2005, unless otherwise noted.

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.

*Outreach program*s 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).

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.

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.

[70 FR 57374, Sept. 30, 2005, as amended at 71 FR 48143, Aug. 18, 2006]

§ 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 beneficiaries, 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 beneficiaries 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 beneficiary must provide required documentation in a timely manner.

(b) *Schedule of loan.* A loan beneficiary 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 beneficiary 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 beneficiary 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 beneficiary to begin making payments of principal or interest at the end of the 60-month deferment period if it determines that the loan beneficiary meets the criteria for loan forgiveness under section 1897 of the Act, as determined by the Secretary.

(e) *Default.* If a loan beneficiary fails to make any payment in repayment of a loan under this subpart within 10 days of its due date, the loan beneficiary 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 beneficiary 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 beneficiary 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 beneficiary.

(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 beneficiary has the right to make payments of principal at any time before they are due. A loan beneficiary may make full prepayment or partial prepayment without paying any prepayment charge. If a prepayment is made, the loan beneficiary 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 beneficiary 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 beneficiary 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—Forgiveness of Indebtedness

SOURCE: 71 FR 48144, Aug. 18, 2006, unless otherwise noted.

§ 505.13 Conditions for loan forgiveness.

The Secretary may forgive a loan provided under this part if the qualifying hospital—

(a) Has been selected to participate in the loan program specified in § 505.5(c).

(b) Has established the following in accordance with a plan that meets the criteria specified in § 505.15:

(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, beginning one year from the date that CMS notified the qualifying hospital of the loan award, the qualifying hospital must submit a report to CMS that updates the plan specified in § 505.15 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. If CMS determines that the annual report shows that the qualifying hospital has fulfilled the conditions, plan criteria, and reporting requirements for loan forgiveness specified in §§ 505.13, 505.15, and 505.17, CMS will notify the qualifying hospital in writing that the loan is forgiven.

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

§ 505.19 Approval or denial of loan forgiveness.

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

(1) 30 days from the date of receipt of the annual report that shows the qualifying hospital has satisfied the requirements for loan forgiveness; or

(2) 90 days before the end of the loan deferment period defined in § 505.7(b).

(b) *Denial of loan forgiveness.* If CMS determines that 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 of loan forgiveness to the qualifying hospital at least 30 days before the end of the loan deferment period defined in § 505.7(b).

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

Subpart A—General Provisions

Sec.

Subpart B—Comprehensive Care for Joint Replacement Program Participants