PART 505—ESTABLISHMENT OF THE
HEALTH CARE INFRASTRUCTURE
IMPROVEMENT PROGRAM

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 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).

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]
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 de-
ducted 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 beneficiary has the right to make
   payments of principal at any time be-
   fore they are due. A loan beneficiary
   may make full prepayment or partial
   prepayment without paying any pre-
   payment charge. If a prepayment is
   made, the loan beneficiary must pro-
   vide written notice to CMS at CMS, Di-
   vision 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 ap-
   proval 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 pri-
   vate 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 require-
ments and procedures.

(a) The loan application must be re-
   ceived 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 de-
   liver an original copy of the loan to
   CMS. The loan application must con-
   tain the following information:
   (1) Qualifying hospital’s name and
   street address.
   (2) Qualifying hospital’s Medicare
   provider number.
   (3) Name, title, and telephone num-
   ber of a contact person submitting the
   application.
   (4) Provide all appropriate supporting
   documentation for each answer made
   on the loan application.

§ 505.13 Conditions for loan forgive-
ness.

The Secretary may forgive a loan
provided under this part if the quali-
ifying 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 treat-
   ment that provides services to a sub-
   stantial majority of the residents of a
   State or region, including residents of
   rural areas;
   (2) An outreach program for cancer
   prevention, early diagnosis, and treat-
   ment that provides services to multiple
   Indian tribes; and
   (3) Unique research resources (such
   as population databases) or an affili-
   ation with an entity that has unique
   research resources.
   (c) Submits to CMS, within the time-
   frame specified by the Secretary, a—
   (1) Written request for loan forgive-
   ness; 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, im-
plement, or maintain an existing out-
reach 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 quali-
fying hospital will establish or main-
tain 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 can-
cer(s) during the loan deferment pe-
riod;

(3) Address cancer treatment for can-
cers that are prevalent in the des-
ignated 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 hos-
pital'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 hos-
pital will establish or maintain exist-
ing unique research resources or an af-
filiation with an entity that has unique
research resources.

§ 505.17 Reporting requirements for
meeting the conditions for loan for-
giveness.

(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 hos-
pital'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 an-
nual report to provide the hospital
with feedback regarding its loan for-
giveness 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 spec-
cified 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 require-
ments. A qualifying hospital must sub-
mit 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 for-
giveness.

(a) Approval of loan forgiveness. If
CMS determines that a qualifying hos-
pital has met the conditions, plan cri-
teria, and reporting requirements for
loan forgiveness specified in §§505.13,
505.15, and 505.17, CMS will send a writ-
ten 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 quali-
fying hospital has satisfied the require-
ments 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 cri-
teria, 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 hos-
pital at least 30 days before the end of
the loan deferment period defined in
§505.7(b).