Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals

**Summary:** Prohibits physician-owned hospitals that do not have a provider agreement prior to December 31, 2010, to participate in Medicare. Such hospitals that have a provider agreement prior to December 31, 2010, could continue to participate in Medicare under certain requirements addressing conflict of interest, bona fide investments, and patient safety issues, and expansion limitations.

**Status update:** As part of the proposed 2011 hospital outpatient departments rule released on July 2, 2010, the Center for Medicare and Medicaid Services (CMS) included proposed regulations implementing the new restrictions regarding physician-owned hospitals.

**Next steps:**
- July 2, 2010 – CMS issued proposed rule
- August 31, 2010 – Comments due on proposed rule
- November 1, 2010 – CMS will issue a final rule
- By December 31, 2010 – Must have provider agreement in place
- September 23, 2011 – New limitations on the Medicare exceptions to the prohibition on certain physician referrals for hospitals go into effect; Secretary must establish policies and procedures to ensure compliance with these requirements by this date.
- By January 1, 2012 – Secretary must issue regulations regarding the provision providing a limited exception for the expansion of qualified hospitals
- By February 1, 2012 – Secretary must implement the provision providing a limited exception for the expansion of qualified hospitals
- By May 1, 2012 – Secretary must conduct compliance audits beginning not later than May 1, 2012.

**Additional information:**
Center for Medicare and Medicaid Services (CMS) Specialty Hospital page --
Agency for Healthcare Research and Quality (AHRQ) 2009 article summary examining the
effect of specialty hospitals on other hospital nurse staffing levels --
http://www.ahrq.gov/research/oct09/1009RA7.htm

Long summary:
Sec. 6001. Limitation on Medicare exception to the prohibition on certain physician referrals
for hospitals (as modified by sec. 10601 and by sec. 1106 of HCERA).

Rural provider exception changes. This section adds requirements for rural hospitals to qualify
for the rural provider exception to the prohibition on certain physician self-referrals due to
ownership or investment. Specifically, beginning not later than September 23, 2011, only hospitals
with physician ownership or investment and a provider agreement in operation on December 31,
2010 and that meet numerous specified requirements are exempt from the prohibition on self-
referral.

Requirements. The requirements include:
- an annual report from each such hospital to the Secretary containing a detailed description
  of the hospital’s ownership and investment interests (which the Secretary must disclose
  and update annually on a CMS website);
- disclosure by the hospital on its website and in any public advertising of the fact that
  physicians have ownership or investment interests;
- disclosure to patients concerning any ownership or investment interest of referring or
  treating physicians by a time that permits the patient to make a meaningful decision
  regarding the receipt of care;
- prohibition on the hospital conditioning any physician ownership or investment interests
  either directly or indirectly on a physician owner or investor making or influencing
  referrals;
- limiting the aggregate value of the ownership or investment interests of physician owners
  or investors to the percentage they represented on March 23, 2010;
- various requirements to assure that physicians’ ownership or investment interests do not
  result from special favor from the hospital (such as loans or other assistance in acquiring
  ownership) or provide for future favors (such as the opportunity to benefit from or to
  purchase other business interests related to the hospital); and
- procedures to disclose to patients if a physician will not be available on the premises to
  provide services during all hours in which the hospital is providing services to the patient
  (which also require a signed statement from the patient).

The hospital also could not have converted from an ambulatory surgical center to a hospital on or
after March 23, 2010. Limits the number of operating rooms, procedure rooms, and beds for which
the hospital is licensed at any time on or after March 23, 2010 to the number of operating rooms,
procedure rooms, and beds for which the hospital is licensed on March 23, 2010. Procedure rooms
includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are
performed, except such term shall not include emergency rooms or departments (exclusive of
rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

Expansion in some circumstances. Provides a process to allow qualified hospitals to apply for an
exception to the prohibition on expansion. To qualify for an exception, a hospital must either be (1)
a high Medicaid facility (defined as having an annual percentage of Medicaid admissions that is the highest percentage for all hospitals in the county for each of the three most recent years for which data are available and cannot be the sole hospital in the community) or (2) satisfy five specified criteria – (a) located in a fast-growing County, (b) experiencing average or greater Medicaid percentage of inpatient admissions, (c) not discriminating against beneficiaries of Federal health care programs and not permitting physicians practicing at the hospital to discriminate against such beneficiaries, (d) located in a state with higher than average bed occupancy rates; and (e) located in a state with lower than average bed capacity and higher than average bed occupancy rates.

Limitation on capacity increase. Capacity increase is limited to facilities on the main campus and cannot exceed 200% of the number of operating rooms, procedure rooms and beds on March 23, 2010 or (under certain circumstances December 31, 2010). The Secretary must publish final decisions on an expansion request no later than 60 days after receiving a complete application.

There is no administrative or judicial review of the exceptions process.

Summary of the Regulations:

Compliance requirement. CMS states that compliance with all requirements must occur no later than September 23, 2011, and failure to satisfy earlier deadlines will preclude use of the revised exceptions after the earlier deadline has passed. Most of the provisions within section 1877(i)(1) of the Act do not specify an explicit deadline for compliance. Thus, we are proposing that the deadline for compliance with all provisions within section 1877(i)(1) of the Act that do not contain an explicit deadline is September 23, 2011, that is, 18 months after the date of enactment.

Facility expansion. CMS specifies that the hospital will be limited to the number of operating rooms, procedure rooms, and beds for which the hospital is licensed on March 23, 2010, or if the hospital did not have a provider agreement in effect as of that date, but does have an agreement in effect on December 31, 2010, the effective date of such provider agreement. The limitation on expansion of facility capacity applies to operating rooms, procedure rooms, and beds for which the hospital is licensed, regardless of whether a State licenses these rooms. Referrals are prohibited if made by physician owners and investors after facility expansion and prior to the Secretary's granting of an exception to the capacity restriction. Exceptions for expanding facility capacity will protect only those referrals made after the exception is granted.

Physician ownership. (i) If a hospital had no physician ownership or investment as of March 23, 2010, it will not qualify for the whole hospital or rural provider exceptions if it adds any physician owners or investors after that date; and (ii) if a hospital had physician ownership or investment as of March 23, 2010, it may reduce the number of physician owners or investors, provided that the percentage of the total value of physician ownership or investment interests, in the aggregate, remains the same or decreases.

Patient safety requirements. The new patient safety requirements (related to patient disclosure if no physician is available on the premises to provide services during all hours in which the hospital is providing services to such patient) apply to both inpatient and outpatient settings. CMS further specifies that, in the case of a hospital where a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, before admitting a patient or providing an outpatient service, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are rendered to the patient.
**Additional rulemaking.** CMS plans to issue additional rulemaking to (1) establish the process by which to receive an exception to the facility expansion and (2) annual reporting to ensure compliance with the statute. In addition, CMS may provide (1) additional guidance regarding bona fide investment and (2) information regarding audits.

**Request for comments:**

- Although the statute would allow “procedure rooms” to include additional rooms, CMS is not proposing to do so at this time and encourages public comment on whether “procedure rooms” should include rooms where additional services, such as CT or PET scans, or other services, are performed.
- With respect to the latest regulations surrounding conflicts of interest, CMS is soliciting public comments on the following:
  - Benefits and drawbacks of our proposal relating to the procedures hospitals must have in place to require referring physician owners and investors to make the required patient disclosures, including information about other methods and alternative approaches to address this issue and what should constitute sufficient hospital procedures to require such disclosures to a patient by a referring physician owner or investor.
  - Given that a patient may have multiple conditions for which there are a variety of physician specialists who are responsible for different aspects of a patient's care, the statute refers to a single “treating physician.” CMS is not proposing to define “treating physician,” but will consider treating physicians to be those physicians who are responsible for any aspect of a patient’s care or treatment. CMS welcomes public comments on this approach.
  - Methods a hospital should be required to use in disclosing its physician ownership or investment in public advertising, specifically, whether a hospital should be required to disclose physician ownership or investment on its homepage, any particular page on its Web site (for example, an “About Us” page), or all pages on its Web site; the types of media that constitute, or do not constitute, public advertising; and whether a minimum font size should be required for the disclosure.

**Legislative text:**

SEC. 6001. LIMITATION ON MEDICARE EXCEPTION TO THE PROHIBITION ON CERTAIN PHYSICIAN REFERRALS FOR HOSPITALS.

(a) In General.—Section 1877 of the Social Security Act (42 U.S.C. 1395nn) is amended—

(1) in subsection (d)(2)—

(A) in subparagraph (A), by striking “and” at the end;

(B) in subparagraph (B), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph (3)(D).”; and

(2) in subsection (d)(3)—

(A) in subparagraph (B), by striking “and” at the end;

(B) in subparagraph (C), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(D) the hospital meets the requirements described in subsection (i)(1) not later than 18 months after the date of the enactment of this subparagraph.”; and

(3) by adding at the end the following new subsection:

“(i) Requirements for Hospitals To Qualify for Rural Provider and Hospital Exception to Ownership or Investment Prohibition.—
“(1) REQUIREMENTS DESCRIBED.—For purposes of subsection (d)(3)(D), the requirements described in this paragraph for a hospital are as follows:

‘‘(A) PROVIDER AGREEMENT.—The hospital had—

‘‘(i) physician ownership or investment on December 31, 2010;
‘‘(ii) a provider agreement under section 1866 in effect on such date.

‘‘(B) LIMITATION ON EXPANSION OF FACILITY CAPACITY.—Except as provided in paragraph (3), the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after the date of the enactment of this subsection is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date.

‘‘(C) PREVENTING CONFLICTS OF INTEREST.—

‘‘(i) The hospital submits to the Secretary an annual report containing a detailed description of—

‘‘(I) the identity of each physician owner or investor and any other owners or investors of the hospital; and
‘‘(II) the nature and extent of all ownership and investment interests in the hospital.

‘‘(ii) The hospital has procedures in place to require that any referring physician owner or investor discloses to the patient being referred, by a time that permits the patient to make a meaningful decision regarding the receipt of care, as determined by the Secretary—

‘‘(I) the ownership or investment interest, as applicable, of such referring physician in the hospital; and
‘‘(II) if applicable, any such ownership or investment interest of the treating physician.

‘‘(iii) The hospital does not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

‘‘(iv) The hospital discloses the fact that the hospital is partially owned or invested in by physicians—

‘‘(I) on any public website for the hospital; and
‘‘(II) in any public advertising for the hospital.

‘‘(D) ENSURING BONA FIDE INVESTMENT.—

‘‘(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of the date of enactment of this subsection.

‘‘(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

‘‘(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

‘‘(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

‘‘(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

‘‘(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

‘‘(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

‘‘(E) PATIENT SAFETY.—

‘‘(i) Insofar as the hospital admits a patient and does not have any physician available on the premises to provide services during all hours in which the hospital is providing services to such patient, before admitting the patient—

‘‘(I) the hospital discloses such fact to a patient; and
‘‘(II) following such disclosure, the hospital receives from the patient a signed acknowledgment that the patient understands such fact.

‘‘(ii) The hospital has the capacity to—

‘‘(I) provide assessment and initial treatment for patients; and
‘‘(II) refer and transfer patients to hospitals with the capability to treat the needs of the patient involved.

‘‘(F) LIMITATION ON APPLICATION TO CERTAIN CONVERTED FACILITIES.—The hospital was not converted from
an ambulatory surgical center to a hospital on or after the date of enactment of this subsection.

"(2) PUBLICATION OF INFORMATION REPORTED.—The Secretary shall publish, and update on an annual basis, the information submitted by hospitals under paragraph (1)(C)(i) on the public Internet website of the Centers for Medicare & Medicaid Services.

"(3) EXCEPTION TO PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—

"(A) PROCESS.—

"(i) ESTABLISHMENT.—The Secretary shall establish and implement a process under which a hospital that is an applicable hospital (as defined in subparagraph (E)) or is a high Medicaid facility described in subparagraph (F) may apply for an exception from the requirement under paragraph (1)(B).

"(ii) OPPORTUNITY FOR COMMUNITY INPUT.—The process under clause (i) shall provide individuals and entities in the community in which the applicable hospital applying for an exception is located with the opportunity to provide input with respect to the application.

"(iii) TIMING FOR IMPLEMENTATION.—The Secretary shall implement the process under clause (i) on February 1, 2012.

"(iv) REGULATIONS.—Not later than January 1, 2012, the Secretary shall promulgate regulations to carry out the process under clause (i).

"(B) FREQUENCY.—The process described in subparagraph (A) shall permit an applicable hospital to apply for an exception up to once every 2 years.

"(C) PERMITTED INCREASE.—

"(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), an applicable hospital granted an exception under the process described in subparagraph (A) may increase the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed above the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital (or, if the applicable hospital has been granted a previous exception under this paragraph, above the number of operating rooms, procedure rooms, and beds for which the hospital is licensed after the application of the most recent increase under such an exception).

"(ii) 100 PERCENT INCREASE LIMITATION.—The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed under clause (i) to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital.

"(iii) BASELINE NUMBER OF OPERATING ROOMS, PROCEDURE ROOMS, AND BEDS.—In this paragraph, the term 'baseline number of operating rooms, procedure rooms, and beds' means the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of the date of enactment of this subsection (or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement).

"(D) INCREASE LIMITED TO FACILITIES ON THE MAIN CAMPUS OF THE HOSPITAL.—Any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed pursuant to this paragraph may only occur in facilities on the main campus of the applicable hospital.

"(E) APPLICABLE HOSPITAL.—In this paragraph, the term ‘applicable hospital’ means a hospital—

"(i) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date of the application under subparagraph (A)) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located, as estimated by Bureau of the Census;

"(ii) whose annual percent of total inpatient admissions that represent inpatient admissions under the program under title XIX is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;

"(iii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

"(iv) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and

"(v) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located.

"(F) HIGH MEDICAID FACILITY DESCRIBED.—A high Medicaid facility described in this subparagraph is a hospital that—

"(i) is not the sole hospital in a county;
“(ii) with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions that represent inpatient admissions under title XIX that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and

“(iii) meets the conditions described in subparagraph (E)(iii).

“(G) PROCEDURE ROOMS.—In this subsection, the term ‘procedure rooms’ includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

“(H) PUBLICATION OF FINAL DECISIONS.—Not later than 60 days after receiving a complete application under this paragraph, the Secretary shall publish in the Federal Register the final decision with respect to such application.

“(I) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this paragraph (including the establishment of such process).

“(4) COLLECTION OF OWNERSHIP AND INVESTMENT INFORMATION.—For purposes of subparagraphs (A)(i) and (D)(i) of paragraph (1), the Secretary shall collect physician ownership and investment information for each hospital.

“(5) PHYSICIAN OWNER OR INVESTOR DEFINED.—For purposes of this subsection, the term ‘physician owner or investor’ means a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital.

“(6) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the Secretary from revoking a hospital’s provider agreement if not in compliance with regulations implementing section 1866.”.

(b) ENFORCEMENT.—

(1) ENSURING COMPLIANCE.—The Secretary of Health and Human Services shall establish policies and procedures to ensure compliance with the requirements described in subsection (i)(1) of section 1877 of the Social Security Act, as added by subsection (a)(3), beginning on the date such requirements first apply. Such policies and procedures may include unannounced site reviews of hospitals.

(2) AUDITS.—Beginning not later than May 1, 2012, the Secretary of Health and Human Services shall conduct audits to determine if hospitals violate the requirements referred to in paragraph (1).