State law or regulation governing billing or claims submission.

(13) The transfer of the items or services occurs and all conditions in this paragraph (w) are satisfied on or before December 31, 2021.

[72 FR 51091, Sept. 5, 2007; 72 FR 68076, Dec. 4, 2007, as amended at 73 FR 48752, Aug. 19, 2008; 73 FR 57543, Oct. 3, 2008; 78 FR 78768, Dec. 27, 2013]

§411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of Inspector General (OIG) concerning their reportable financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times that CMS or OIG specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) or the national provider identifier (NPI) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN or NPI of each physician who has an immediate family member (as defined at §411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at §411.354(b) or any compensation arrangement, as defined at §411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in §411.356(a) or §411.356(b) regarding publicly-traded securities and mutual funds.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that information and documentation available to CMS or OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 for each day following the deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

[72 FR 51098, Sept. 5, 2007]

§411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) *Definitions.* For purposes of this section—

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a

provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement).

External data source means a data source that—

(1) Is generated, maintained, or under the control of a State Medicaid agency;

(2) Is reliable and transparent;

(3) Maintains data that, for purposes of the process described in paragraph (c) of this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(4) Maintains or generates data that, for purposes of the process described in paragraph (c) of this section, are accurate, complete, and objectively verifiable.

Main campus of the hospital means ''campus'' as defined at § 413.65(a)(2).

Physician owner or investor means a physician (or immediate family member of the physician) with a direct or an indirect ownership or investment interest in the hospital.

Procedure room means a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

(b) *General requirements.* (1) *Physician ownership and provider agreement.* The hospital had physician ownership or investment on December 31, 2010; and a provider agreement under section 1866 of the Act in effect on that date.

(2) *Prohibition on facility expansion.* The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is granted pursuant to paragraph (c) of this section.

(3) *Disclosure of conflicts of interest.* (i) At such time and in such manner as specified by CMS, the hospital must submit an annual report to CMS containing a detailed description of the identity of each owner or investor in the hospital and the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital must—

(A) Require each referring physician owner or investor who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment interest in the hospital (and, if applicable, the ownership or investment interest of any treating physician) to all patients whom the physician refers to the hospital. Disclosure must be required by a time that permits the patient to make a meaningful decision regarding the receipt of care.

(B) 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.

(C) Disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians.

(4) *Ensuring bona fide investment.* The hospital satisfies the following criteria:

(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 March 23, 2010.

(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.

(5) *Patient safety*. The hospital satisfies the following criteria:

(i) If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient. Before providing services to the patient, 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 furnished to the patient.

(ii) The hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address. For purposes of this paragraph, the hospital inpatient stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service.

(6) *Prohibition on conversion from an ambulatory surgery center*. The hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

(c) *Criteria for an individual hospital seeking an exception to the prohibition on facility expansion*—(1) *General*. An applicable hospital or high Medicaid facility may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

(2) *Criteria for applicable hospital*. An applicable hospital is a hospital that satisfies all of the following criteria:

(i) *Population increase*. Is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(ii) *Medicaid inpatient admissions*. Has an annual percent of total inpatient admissions under Medicaid that 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 during the most recent 12-month period for which data are available as of the date that the hospital submits its request. For purposes of this paragraph, the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

(iii) *Nondiscrimination.* 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) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. CMS will provide on its Web site State average bed capacities and the national average bed capacity. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS, that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. A hospital must use filed hospital cost report data to determine its average bed occupancy rate. CMS will provide on its Web site State average bed occupancy rates. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS, that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

(3) *Criteria for high Medicaid facility.* A high Medicaid facility is a hospital that satisfies all of the following criteria:

(i) *Sole hospital.* Is not the sole hospital in the county in which the hospital is located.

(ii) *Medicaid inpatient admissions.* With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid 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. For purposes of this paragraph, the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and every hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(iii) *Nondiscrimination.* Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the

hospital to discriminate against such beneficiaries.

(4) *Procedure for submitting a request.*

(i) A hospital must either mail an original and one copy of the written request to CMS or submit the request electronically to CMS. If a hospital submits the request electronically, the hospital must mail an original hard copy of the signed certification set forth in paragraph (c)(4)(iii) of this section to CMS.

(ii) A request must include the following information:

(A) The name, address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital requesting an exception.

(B) The county in which the hospital requesting an exception is located.

(C) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital.

(D) A statement identifying the hospital as an applicable hospital or high Medicaid facility and a detailed explanation with supporting documentation regarding whether and how the hospital satisfies each of the criteria for an applicable hospital or high Medicaid facility. The request must state that the hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(E) Documentation supporting the hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(iii) A request must include the following certification signed by an authorized representative of the hospital: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief.'' An authorized representative is the chief executive officer, chief financial officer, or other comparable officer of the hospital.

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the FEDERAL REGISTER. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(i) If only filed Medicare hospital cost report data are used in the hospital's request, the written comments, and the hospital's rebuttal statement—

(A) A request will be deemed complete at the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete at the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(ii) If data from an external data source are used in the hospital's request, the written comments, or the hospital's rebuttal statement—

(A) A request will be deemed complete no later than 180 days after the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete no later than 180 days after the

end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(6) A permitted increase under this section—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(7) *Publication of final decisions.* Not later than 60 days after receiving a complete request, CMS will publish the final decision in the FEDERAL REGISTER.

(8) *Limitation on review.* There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this section (including the establishment of such process).

[75 FR 72260, Nov. 24, 2010, as amended at 76 FR 74581, Nov. 30, 2011; 79 FR 67029, Nov. 10, 2014]

§ 411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS accepts requests.* The provisions of § 411.370 through § 411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, CMS determines whether a business arrangement described by the parties to that arrangement appears to constitute a ''financial relationship'' (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* CMS does not address through the advisory opinion process—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* CMS considers requests for advisory opinions that involve applying specific facts to the subject matter described in paragraph (b) of this section. Requestors must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in § 411.372.

(e) *Requests that will not be accepted.* CMS does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity;

(2) CMS is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other