

intermediaries and CMS on adjustment payments that were adjudicated during FY 2007. As indicated above, the adjustments made during FY 2007 only pertain to cost reporting periods ending

in years prior to FY 2006. Total adjustment payments given to excluded hospitals and units during FY 2007 are \$9,862,685. The table depicts for each class of hospitals, in the aggregate, the

number of adjustment requests adjudicated, the excess operating cost over ceiling, and the amount of the adjustment payments.

| Class of hospital                 | Number | Excess cost over ceiling | Adjustment payments |
|-----------------------------------|--------|--------------------------|---------------------|
| Psychiatric .....                 | 13     | \$8,223,003              | \$3,756,831         |
| Long-Term Care .....              | 1      | 4,962,747                | 584,150             |
| Children's .....                  | 2      | 1,082,666                | 824,308             |
| Cancer .....                      | 2      | 7,168,945                | 3,186,072           |
| Religious Nonmedical Health ..... |        |                          |                     |
| Care Institution .....            | 11     | 3,619,026                | 1,511,324           |
| <b>Total .....</b>                |        |                          | <b>9,862,685</b>    |

#### VII. Disclosure Required of Certain Hospitals and Critical Access Hospitals (CAHs) Regarding Physician Ownership (§ 489.2(u) and (v))

Section 1866 of the Act states that any provider of services (except a fund designated for purposes of sections 1814(g) and 1835(e) of the Act) shall be qualified to participate in the Medicare program and shall be eligible for Medicare payments if it files with the Secretary a Medicare provider agreement and abides by the requirements applicable to Medicare provider agreements. These requirements are incorporated into our regulations in 42 CFR part 489, subparts A and B.

In the FY 2008 IPPS final rule with comment period, we revised our regulations governing Medicare provider agreements, specifically § 489.20(u), to require a hospital to disclose to all patients whether it is physician-owned and, if so, the names of its physician owners (72 FR 47385 through 47387). In addition, we added a definition of physician-owned hospital at § 489.3. (Because the definition of physician-owned hospital at § 489.3 includes a critical access hospital, for ease of reference and readability, the term "hospital," when used in the context of a physician-owned hospital, is intended to include a CAH.) The disclosure requirement in current § 489.20(u), as amended by the FY 2008 IPPS final rule with comment period, is applicable only to those hospitals with physician ownership; we neglected to include those hospitals in which no physician held an ownership or investment interest, but in which an immediate family member of a referring physician held an ownership or investment interest. However, it was always our intent to have consistency between the disclosure requirements and the physician self-referral statute and regulations. The physician self-

referral statute and regulations, which recognize the potential for program and patient abuse where a financial relationship exists, are applicable to both a physician and the immediate family member of the physician. Therefore, in the FY 2009 IPPS proposed rule, we proposed to revise the language in § 489.3 to define a "physician-owned hospital" as a participating hospital in which a physician, or an immediate family member of a physician (as defined at § 411.351), has an ownership or investment interest in the hospital (73 FR 23683). In this final rule, we are finalizing our proposal. We believe that it is necessary to revise our definition of physician-owned hospital because a physician's potential conflict of interest occurs not only in those instances where he or she has a financial relationship in the form of an ownership or investment interest, but also where his or her immediate family member has a similar interest, and patients should be informed of this as part of making an informed decision concerning treatment.

Following publication of the FY 2008 IPPS final rule with comment period, we became aware that some physician-owned hospitals have no physician owners who refer patients to the hospital (for example, in the case of a hospital whose physician-owners have retired from the practice of medicine). In the FY 2009 IPPS proposed rule, we proposed to include in § 489.20(v) new language to provide for an exception to the disclosure requirements for a physician-owned hospital (as defined at § 489.3) that does not have any physician owners who refer patients to the hospital (and that has no referring physicians (as defined at § 411.351) who have an immediate family member with an ownership or investment interest in the hospital), provided that the hospital attests, in writing, to that effect and

maintains such attestation in its files for review by State and Federal surveyors or other government officials (73 FR 23683). In this final rule, we are finalizing our proposal. We believe that requiring a hospital with no referring physician owners to disclose to all patients that it is physician-owned and to provide the patients with a list of the (nonreferring) physician owners would be an unnecessary burden on the hospital and of no value in assisting a patient in making an informed decision as to where to seek treatment. Similarly, we do not believe that it is useful to require a hospital to make such disclosures when no referring physician has an immediate family member who has an ownership or investment interest in the hospital.

In the FY 2009 IPPS proposed rule, we proposed to revise § 489.20(u) to specify that a physician-owned hospital must furnish to patients the list of owners and investors who are physicians (or immediate family members of physicians) at the time the list is requested by or on behalf of the patient (73 FR 23683). (Currently, § 489.20(u) provides that a physician-owned hospital must provide a list of its owners and investors to patients but does not specify when the list must be provided.) In this final rule, we are finalizing our proposal. We believe that it is critical that the patient receives the list of names of the relevant owners or investors at the time the request is made by or on behalf of the patient so that the patient may make a determination as to whether his or her admitting or referring physician has a potential conflict of interest. Also, furnishing the list at the time the request is made by the patient or on behalf of the patient is crucial to affording the patient an opportunity to make an informed decision before treatment is furnished at the physician-owned hospital.

In addition, we proposed to add new § 489.20(u)(2) to require a physician-owned hospital to require all physicians who are members of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients whom they refer to the hospital any ownership or investment interest in the hospital held by themselves or by an immediate family member (73 FR 23684). We proposed to require that physicians agree to make such disclosures at the time they refer patients to the hospital. In this final rule, we are finalizing our proposal. We believe that early notification of physician ownership or investment in the hospital is beneficial to the patient's decision-making concerning his or her treatment. Requiring a physician to notify patients of his or her ownership or investment interest at the time of the referral will afford patients the opportunity to discuss the physician's ownership or investment interest in the hospital and make a more informed decision.

In the FY 2009 IPPS proposed rule, we also proposed to revise § 489.53 to permit CMS to terminate the Medicare provider agreement if a physician-owned hospital fails to comply with the provisions of proposed § 489.20(u), discussed above, or if a hospital or CAH fails to comply with the requirements set forth in § 489.20(v) (which we proposed to redesignate as § 489.20(w) (73 FR 23684 through 23685)). (In the FY 2008 IPPS final rule with comment period, we added a new provision at § 489.20(v) to require that hospitals and CAHs: (1) Furnish all patients written notice at the beginning of their inpatient hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week; and (2) describe how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present in the hospital or CAH (72 FR 47387).) In this final rule, we are finalizing these proposals. We believe that these revisions are necessary to enforce the disclosure requirements set forth in § 489.20(v) and redesignated § 489.20(w).

We received approximately 20 public comments, most of which were supportive of our proposals. After consideration of the public comments received, we are adopting, with some modification, our proposals as final. The new provisions are codified in revised §§ 489.3, 489.20(u), (v), and (w), and 489.53. We stated in our proposal with respect to redesignated § 489.20(w), that

we were proposing to revise § 489.53 to permit CMS to terminate the Medicare provider agreement of any hospital or CAH that fails to comply with the requirements set forth in proposed redesignated § 489.20(w) (73 FR 23684). This proposal was consistent with the current rule's application to all hospitals and CAHs that do not have a physician on-site 24 hours per day, 7 days per week. However, our proposed revisions to the regulatory text inadvertently were worded so as to imply that this enforcement action could be taken only in the case of a violation by a physician-owned hospital. In this final rule, we are amending the proposed regulatory text of § 489.53(c) by adding language so that the provision of paragraph (c) applies to all hospitals and CAHs (and not just physician-owned hospitals and CAHs) covered by redesignated § 489.20(w). In response to our solicitation of comments regarding whether hospitals and CAHs should educate patients about the availability of information regarding physician ownership under the proposed disclosure requirements, we are not adopting any such requirement at this time.

*Comment:* Most commenters strongly supported our proposals to: (1) Revise the definition of a physician-owned hospital to include hospitals in which an ownership interest is held by a physician or his or her immediate family member; (2) require hospitals to provide to the patient at the time the list is requested, by or on behalf of the patient, the names of each physician and immediate family member with an ownership interest in the hospital; (3) create an exception to the disclosure requirements for a physician-owned hospital (as defined at revised § 489.3) that does not have any physician owners who refer patients to the hospital (and that has no referring physicians (as defined at § 411.351) who have an immediate family member with an ownership or investment interest in the hospital); and (4) terminate the Medicare provider agreement of a hospital that does not comply with the disclosure requirements set forth in revised §§ 489.20(u)(1) and (u)(2), and redesignated § 489.20(w). One commenter contended that receiving the list of physician owners after admission occurs or even at the point of registration is too late to provide a meaningful period of discussion and reflection, and an opportunity for the patient to make a choice. The commenter asserted that the amendments and enhancements in the proposed rule will enable informed

patient decisions and strengthen transparency in physician financial relationships that may conflict with a patient's best interest.

*Response:* We are adopting our proposals as final for the reasons stated above (see §§ 489.3, 489.20(u)(1) and (u)(2), (v), and (w), and 489.53).

*Comment:* One commenter, supportive of the proposed revisions regarding disclosure of a physician's, or his or her immediate family member's, ownership or investment interest in a hospital, recommended that we state in the final rule that physician financial interests in hospitals to which they refer patients is viewed positively by patients and that such interests should not be presumed to be improper or inappropriate.

*Response:* We are not adopting the language suggested by the commenter because we do not want to take any position as to whether or not patients are generally satisfied with physician ownership. With respect to the commenter's suggestion that we state affirmatively that physician ownership should not be presumed to be improper or inappropriate, we cannot adopt such language. As we stated in the FY 2008 IPPS final rule with comment period (72 FR 47388), we believe that the physician ownership disclosure requirement would permit an individual to make more informed decisions regarding his or her treatment and to evaluate whether the existence of a financial relationship, in the form of an ownership interest, suggests a conflict of interest that is not in the patient's best interest. We believe that our preamble language is consistent with the statute and there is no basis for incorporating the language recommended by the commenter. We believe patients will be able to make appropriate use of information disclosed by hospitals regarding ownership by physicians or their immediate family members. However, disclosure to patients, standing alone, does not adequately protect against inappropriate referrals by health care providers and practitioners.

*Comment:* Several commenters requested that we revisit our requirement in § 489.20(v) (now redesignated as § 489.20(w)) that a hospital that does not have a physician on the hospital premises 24 hours per day, 7 days per week, disclose this fact to all patients and describe how the hospital would treat patients with an emergency medical condition. The commenters suggested that the requirement be limited to inpatient admissions only and those outpatient visits that include surgery, other

invasive procedures, use of general anesthesia or other high-risk treatment. In addition, the commenters recommended that emergency department services be excluded. One commenter contended that the intended focus of the requirement was on physician-owned specialty hospitals, arguing that full-service community hospitals are part of a network of care and that there is no need for them to be subject to this requirement. Two commenters objected to the patient notification requirements on the basis that they are particularly burdensome to CAHs and small rural hospitals.

*Response:* The issues raised, and the suggestions made, by the commenters are outside the scope of the provisions of the proposed rule, as we did not propose to make any changes to the patient notification requirements in redesignated § 489.20(w). We will take into consideration, for purposes of possible future rulemaking, the comments that the notification requirements be limited to inpatient admissions only and certain outpatient visits, and that emergency department services be excluded. We note that we do not agree with the commenters who asserted that this requirement should be applied only to physician-owned specialty hospitals, for the reasons that we stated in the FY 2008 IPPS final rule with comment period (72 FR 47388), nor do we agree with the commenter that suggested the notification requirements should not apply to CAHs and small rural hospitals. It is important for consumers to be informed whether or not a physician is always on site, and how emergency medical conditions will be handled when no physician is available. In this regard, we note that there are no restrictions on the types of services CAHs and small rural hospitals may provide, as compared to other types of hospitals. Moreover, we do not believe the patient notification requirements are onerous for any type or size of hospital.

*Comment:* One commenter concurred that proposed enforcement through the possibility of termination of the individual physician's Medicare provider agreement for noncompliance is appropriate. A second commenter recommended that we provide clarification of what form of investigative and administrative procedures CMS will follow in order to provide hospitals and CAHs "due process" prior to terminating a Medicare provider agreement. A third commenter requested clarification of CMS' enforcement mechanism, and urged CMS to implement a progressive discipline system with termination of

the Medicare provider agreement as the final, rather than the only, step.

*Response:* We believe that the commenters misunderstood either our proposal or our procedures for terminating Medicare provider agreements. We did not propose to take action against individual physicians as a result of violations of § 489.20(u) and redesignated § 489.20(w). (We note that physicians do not enter into Medicare provider agreements.) The requirements in § 489.20(u) and redesignated § 489.20(w) apply to hospitals and CAHs and, thus, the termination action provided for in § 489.53(c) also applies to hospitals and CAHs. When CMS takes enforcement action pursuant to § 489.53, it follows the procedures described in section 3030 of the State Operations Manual. In brief, the CMS Regional Office will base its termination action on documentation that supports a finding that the hospital or CAH is not complying with the terms of the Medicare provider agreement, in this case § 489.20(u)(1) or (u)(2), or § 489.20(w). The CMS Regional Office provides a preliminary notice of termination to the hospital or CAH by letter, giving it time to correct the deficiency and come into compliance. If the hospital or CAH provides credible evidence in a timely manner that the cause for termination has been removed, CMS does not proceed with formal termination action. CMS may or may not require a survey of the hospital or CAH to confirm the correction of the deficient practice. If the hospital or CAH fails to come into compliance within the allotted timeframe, the CMS Regional Office issues a formal termination notice to the provider. The public is also provided advance notice of CMS' intent to terminate the Medicare provider agreement. The notice to the provider includes details of the hospital or CAH's appeal rights and information about where to file an appeal. This process is generally the same one used when CMS determines that a hospital or CAH fails to comply with a Medicare CoP, or with the requirements of the EMTALA.

*Comment:* Several commenters responded to our solicitation of comments regarding whether hospitals and CAHs should educate patients about the availability of information regarding physician ownership under the proposed disclosure requirements. One commenter questioned the utility of mandating additional signage or other educational materials. The commenter asserted that patients are already confronted with visual "clutter" in waiting/admitting rooms, and stated that any additional requirements to educate patients on ownership interests

are redundant in light of the other disclosure proposals included in the FY 2009 IPPS proposed rule. A second commenter also expressed opposition to the proposal that hospitals educate patients about the availability of information regarding physician ownership. The commenter opposed the education requirement "due to the lack of research that a patient's knowledge of physician ownership of a hospital affects a patient's choice of hospital," and asserted that the proposal would represent an unnecessary burden.

*Response:* At this time, we are not adopting a requirement that hospitals educate patients regarding physician ownership in hospitals. We believe that the provisions in §§ 489.20(u)(1) and (u)(2) will provide patients with prompt and sufficient notification of a physician's or immediate family member's ownership or investment interest in the hospital.

## VIII. Physician Self-Referral Provisions (§§ 411.351, 411.352, and 411.354)

### A. General Overview

#### 1. Statutory Framework and Regulatory History

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS rendered as a result of a prohibited referral. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. The current version of section 1877 of the Act, which applies to referrals for 11 DHS, has been in effect and subject to enforcement since January 1, 1995. The following is a chronology of relevant physician self-referral rules published in the *Federal Register*.

- January 9, 1998—*Proposed rule* (63 FR 1659)
- January 4, 2001—*Phase I of the final rulemaking*—(Phase I)—Final rule with comment period; effective January 4, 2002 (66 FR 856)
- March 26, 2004—*Phase II of the final rulemaking*—(Phase II)—Interim final rule with comment period; effective July 26, 2004 (69 FR 16054)