Health Care Reform, Transparency, and Program Integrity

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Discussion of health care reform has filled the national press for much of 2009, continuing into 2010. Included in the massive legislation are “program integrity provisions” addressing business relationships of providers, disclosure, and enforcement that will impact the health care industry if adopted.

INTRODUCTION

As this discussion is being prepared, a Health Care Reform Bill has passed both houses of Congress. However, the election of a new Republican senator in Massachusetts has cast doubt on passage of the full bill. Significant differences between the bills passed in the Senate and the House were the subject of intense negotiation between House and Senate leaders. The issues that divide the bills and that have drawn attention in the popular press include financing mechanisms, state versus federal health care exchanges, and whether to include a “public option.” However, the program integrity provisions that are summarized in this discussion are similar between the two bills and have been the subject of little public controversy.

This discussion focuses on some of the provisions contained in Title VI of the Senate Bill, provisions that may become law with few modifications if, as has been discussed, a scaled-back version of the legislation is adopted.

PHYSICIAN OWNERSHIP OF HOSPITALS

The Stark Law, 42 U.S.C. Section 1395nn, as originally adopted in 1989 (effective January 1992), generally prohibited physician ownership of clinical laboratories. In the intervening years, the statute has been expanded to prohibit or constrain financial relationships between physicians and providers of a range of health care services and supplies, including hospital services, radiology services, durable medical equipment, outpatient prescription drugs, home health services, and physical therapy, in addition to clinical laboratory services (collectively referred to as “designated health services”). One of the rationales behind adoption of the Stark Law was that physician ownership of ancillary services leads to increased utilization and cost to the Medicare system. Prohibiting ownership and other financial relationships that tend to reward referrals has been supported in part as a cost control measure.

The statute prohibits an “entity” that provides designated health services from billing Medicare or Medicaid for services ordered by a physician with whom the entity has a financial relationship, unless the financial relationship complies with one of the exceptions in the law. Unlike the Anti-Kickback Statute, which requires proof of intent to induce referrals, the Stark Law was intended to create a “bright line” prohibition on specific types of financial relationships between referring physicians and providers of certain types of health care services, without regard to the parties’ intent or the actual impact of a financial relationship on referral decisions. In practice, however, the Stark Law and its exceptions are extremely complex and require consideration in many types of health care transactions and financial relationships.

Two of the exceptions to the physician ownership prohibition are ownership or investment interests in a “whole hospital” or a “rural provider,” including rural hospitals. The Health Care Reform Bill will place significant limitations on existing...
hospitals that rely on either of these two exceptions, and will not permit development of new physician-owned hospitals that wish to bill Medicare.

The Stark Law exceptions for physician ownership of whole hospitals and rural providers were in part based on the view that in some communities, physicians are one of the few sources of capital available to support a local facility. Perhaps partly in response to the existence of the Stark Law exceptions, however, a trend toward developing “speciality” hospitals emerged. Groups of specialists, such as cardiologists or orthopedic surgeons, developed hospitals that provided specialized hospital services. Community hospitals argued that such hospitals attracted only well-insured patients and high-margin procedures, leaving uninsured and under-insured patients and less profitable procedures to community hospitals.\(^7\)

The concern was initially addressed by adoption of an amendment to the Stark Law, which, effective in late 2003, excluded “speciality hospitals” from the Stark Law “whole hospital” and “rural provider” exceptions.\(^8\) While this exclusion was in place, physicians could not refer Medicare patients to specialty hospitals in which they had ownership interests unless another Stark Law exception applied. The only other exceptions that appear to be potentially applicable are the exceptions for (1) hospitals in Puerto Rico, (2) ownership of publicly traded securities in corporations with shareholder equity in excess of $75 million, (3) services furnished by certain prepaid health plans such as HMOs, or (4) academic medical centers.\(^9\)

When the statutory restriction expired in mid-2005, the Centers for Medicare and Medicaid Services (CMS) adopted a moratorium on processing new provider applications from specialty hospitals.\(^10\) That moratorium ended in 2006. If adopted, the Health Care Reform Bill will prohibit new physician-owned hospitals in the Medicare program, and existing hospitals will be constrained as discussed below. It is worth noting that the Health Care Reform Bill involves a significant expansion of past limitations. Whereas the Stark Law amendment and the CMS moratorium applied only to specialty hospitals, the Health Care Reform Bill will apply to all physician-owned hospitals, including full-service hospitals.

Existing hospitals will be “grandfathered,” or permitted to continue participating in the Medicare program, subject to limitations discussed below. To qualify for grandfathering under the Health Care Reform Bill, an existing hospital must have had physician ownership or investment and a Medicare provider agreement on or before the date provided in the bill.\(^11\) This provision effectively prohibits development of new physician-owned hospitals that wish to participate in Medicare. Even hospitals that are grandfathered face significant new constraints on future expansion and ongoing operations. Hospitals subject to the law:

- may not be licensed for more beds or operating or procedure rooms than they were licensed for on the date of enactment of the bill;
- must make an annual report to the Secretary of the U.S. Department of Health and Human Services (the “Secretary”) with a “detailed description” of each owner or investor in the hospital and the nature and extent of its interests; this information is to be published on the CMS web site;
- must require referring physicians to disclose to patients at “a time that permits the patient to make a meaningful decision regarding receipt of care” the ownership interests of the referring and treating physicians;
- cannot condition ownership on physician referrals or generation of business; and
- must disclose physician ownership on their web sites and in any public advertising.

A process to seek exceptions to the limitations on expansion is to be developed by July 1, 2011. Any allowed increase cannot exceed 100 percent of the “baseline” number of beds or operating rooms as of the enactment date and is limited to facilities on the “main campus” of the hospital. Moreover, hospitals will only be eligible if they are located (1) in counties experiencing a high rate of population growth and (2) in states with below-average bed capacity and above-average bed occupancy rates. The hospital itself must admit at least the average number of Medicaid patients compared to the hospital in its county, something that many physician-owned hospitals may not do.

In addition to the operating restrictions, the Health Care Reform Bill significantly restricts the ability of physician-owned hospitals to modify their ownership structure, expand, or adapt to future changes. Grandfathered hospitals may not increase the percentage of ownership interest held by physicians above that in place on the date of enactment of the bill. The hospital and its owners are prohibited from providing more favorable terms, loans or loan assistance, disproportionate distributions, or other business opportunities to physician investors. Perhaps in response, at least in part, to an incident\(^12\) that occurred in Oregon, hospitals that do not have a physician on site at all times must provide written notice of that fact and obtain patient acknowledgment prior to admission.
Disclosures Required of Physicians

One of the key exceptions under the Stark Law allows physicians in group practices\(^\text{13}\) to own and bill for most designated health services if the group meets the requirements of the in-office ancillary services exception.\(^\text{14}\) Under this exception, groups that meet Stark Law requirements provide imaging, laboratory and other services that would otherwise not be billable to Medicare if the physicians had an ownership interest in the provider.

Reflecting the continuing concern about the potential for overutilization resulting from physician ownership of ancillary services, the Health Care Reform Bill amends the in-office ancillary services exception to require that a referring physician (1) inform a patient in writing at the time of the referral that the patient may obtain the services from another source and (2) provide a list of suppliers in the area. This requirement applies to magnetic resonance imaging, computed tomography, positron emission tomography, and any other radiology services specified by rule.

Whether presentation of yet another form to patients seeking services will have any real impact on utilization, quality, or patient choice seems doubtful. Of concern to affected physicians and medical groups, however, is the potential impact of not having documentation of compliance with the notice requirement in each referred patient’s file in the event of a later audit. The lack of this documentation could become the basis for an assertion of an overpayment and a claim for repayment of the billed amounts. The Health Care Reform Bill\(^\text{15}\) states that this patient notification requirement applies to services furnished after January 1, 2010. Presumably, this date will be pushed back to at least reflect actual enactment of the statute, if not a reasonable period for notice to and implementation by affected physician groups.

Stark Law Self-Disclosure Protocol

One of the most difficult problems presented by the Stark Law has been the enormous financial consequences that can result even from “technical” violations of the law. If a financial relationship between a hospital and a physician does not meet every element of an applicable Stark Law exemption, the Stark Law arguably requires repayment of all amounts paid to the hospital by Medicare with respect to patients admitted or otherwise referred by the physician.\(^\text{16}\) For example, a missing signature on a written contract or a contract with an expired term arguably can result in a financial relationship that does not comply with the Stark Law.\(^\text{17}\)

The Health Care Reform Bill directs the Secretary and the Office of Inspector General (OIG) to develop a self-disclosure protocol for Stark Law violations.\(^\text{18}\) The bill authorizes the Secretary to reduce the amounts owed for Stark Law violations. Factors that may be considered include (1) the nature or extent of the illegal practice, (2) the timeliness of self-disclosure, (3) cooperation in providing additional information, and (4) other factors as determined by the Secretary. The protocol is to be developed within six months of enactment of the Health Care Reform Bill. This protocol should be a vehicle for introducing some much-needed fairness into the application of the Stark Law to technical violations of the rules.

Transparency Reporting

The Health Care Reform Bill adopts new disclosure and reporting requirements covering a wide range of payments and other benefits provided to physicians by drug and device manufacturers and group
purchasing organizations (GPOs).\textsuperscript{19} Manufacturers and GPOs operating in the United States or its territories will be required to report if they produce or deal in devices, drugs, or biological or medical supplies that are covered under Medicare, Medicaid, or the State Children’s Health Insurance Program. “Manufacturer” is broadly defined to include any entity engaged in production, preparation, propagation, compounding, or conversion of a drug, device, or biological or medical supply, or an entity under common ownership that provides assistance or support in such activities or in marketing, promotion, sale or distribution.\textsuperscript{20}

Beginning in 2013,\textsuperscript{21} any manufacturer that “provides a payment or other transfer of value” to, on behalf of or at the direction of a physician or a teaching hospital\textsuperscript{22} will be required to report information annually. The information to be reported includes the following:

1. the name, address, National Provider Identifier and specialty of the recipient
2. the amount, dates and form of payment
3. the nature of the payment (consulting fees, honoraria, gifts, food, travel, education, research, charitable contributions, royalties and grants)

The statute provides a de minimis exclusion for transfers worth less than $10 per item and $100 per year. Also excluded are product samples,\textsuperscript{23} educational materials for patient use, items or services provided under a contractual warranty, discounts, and distributions from publicly traded companies or mutual funds with shareholder equity or total assets of at least $75 million.

In addition, manufacturers and GPOs must disclose annually beginning in 2013\textsuperscript{24} ownership or investment interests of physicians or their family members in the organization during the preceding year. Information to be disclosed includes the amount invested and the terms of the investment. In addition, any payments or transfers of value to such physician investors must be reported as described above. While this requirement appears to duplicate the obligations of manufacturers described above, it imposes those obligations on GPOs with respect to transfers to owner physicians.

Manufacturers and GPOs that fail to make the required reports face fines of $1,000 to $10,000 for each payment not reported, up to a maximum of $150,000 per year. One may speculate that for some drug and device manufacturers, the cost of compliance with the reporting requirements may easily exceed the maximum fine. However, a knowing failure to submit the required information will be subject to fines of $10,000 to $100,000 for each payment or investment interest not reported, up to a maximum fine of $1,000,000 per year.

The Secretary is directed to make the information reported under these provisions available to the public via the Internet—in a searchable format—including manufacturer, GPO and recipient names. However, publication of information concerning payments made in connection with product research or development can be delayed until the annual report following FDA approval, or for four years after payment, whichever is earlier.\textsuperscript{25}

**Changes to Anti-Kickback Statute**

The Health Care Reform Bill modifies the intent requirement under 42 U.S.C. Section 1320a-7b, the Anti-Kickback Statute.\textsuperscript{26} The Anti-Kickback Statute makes it illegal to offer or pay, or to solicit or receive, any “remuneration” in return for or to induce referring, arranging, recommending, purchasing or leasing any item or service for which payment may be made under a federal health care program.

Violation of the statute is a felony and can result in substantial criminal and civil penalties and exclusion from government health care programs. The language of the statute is very broad, and it can be read to apply to many common transactions and relationships. However, the statute requires that a violation be “knowing and willful.” Some courts have interpreted this requirement to require proof of specific intent either to violate the statute or to violate the law.\textsuperscript{27}

The Health Care Reform Bill states that “a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” Whether this change will make the Anti-Kickback Statute a more useful tool for prevention of self-referrals remains to be seen.
ADDITIONAL PROGRAM INTEGRITY PROVISIONS

The Health Care Reform Bill contains many additional provisions that appear to be intended to control fraud and waste in federal health care programs. Some of those provisions are discussed below.

Enrollment

The bill establishes enhanced screening procedures and enhanced disclosures for providers and suppliers enrolling or reenrolling in Medicare and Medicaid. The bill also mandates Medicare application fees of $500 for institutional providers. The Secretary is required to establish procedures for enhanced oversight of new providers during a provisional period of 30 days to one year. The Secretary is also authorized to impose a temporary moratorium on new provider enrollments if necessary to prevent or combat fraud or waste, providing specific statutory authority for the type of moratorium placed on specialty hospitals in 2005 (see endnote 10). State Medicaid programs are required to comply with oversight and moratorium procedures established by the Secretary.

Compliance Programs

Prior to the Health Care Reform Bill, adoption of compliance programs has been primarily voluntary, although the potential impact of not having a compliance plan in the event of a civil fraud allegation has provided a strong incentive for adoption of compliance plans. The OIG has developed specific compliance plans for several types of health care providers, and strongly encourages adoption of compliance plans. The Health Care Reform Bill directs the Secretary to specify categories of providers that must adopt compliance plans, and to develop the “core elements” of compliance plans in consultation with the OIG. State Medicaid programs must require Medicaid providers to meet the requirements established by the Secretary.

Overpayments

Several provisions enhance obligations to refund overpayments and penalties for failure to do so. An express requirement to report and return Medicare and Medicaid overpayments within 60 days of discovery is added to Title XI of the Social Security Act. Overpayments are defined as any funds received or retained under Medicare or Medicaid to which a person is not entitled. Overpayments are made “obligations” under 31 U.S.C. Section 3729(b)(3), making them subject to civil penalties for knowing concealment or avoidance. This provision applies to Medicare Advantage organizations, as well as to providers and suppliers. In addition, a new civil monetary penalty is added to 42 U.S.C. Section 1320a-7a(a) for failure to report and repay an overpayment.

Data Collection, Data Matching, Information Sharing

A variety of provisions address improved data collection, matching of data across agencies of the federal government, and sharing of data between state and federal government. The Health Care Reform Bill requires use of the National Provider Identifier on all claims and applications in Medicare and Medicaid by 2011.

CONCLUSION

The Health Care Reform Bill, if it passes in any form, is likely to include a number of provisions (1) that limit the business relationships of health care providers and others in the health care industry and (2) that impose new requirements for reporting or other disclosure of information about those relationships. Whether or not the bill passes, the program integrity provisions are likely to resurface as the nation struggles with the cost of health care, and fraud and abuse continue to draw attention. Providers and others involved in federal health care programs will face continuing challenges as they seek to maintain viable businesses and to remain in compliance with legal requirements.

Notes:

1. The Senate bill is titled the Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (the “Senate Bill”). The House bill is titled Affordable Health Care for America Act, H.R. 3962, 111th Cong. (the “House Bill”). In this discussion, for ease of reference, the legislation is referred to as the “Health Care Reform Bill.”
2. The provisions addressed in this discussion are contained in Title VI (Sections 6001 through 6801) and Title X, Subtitle F (Sections 10601 through 10609) (Provisions Relating to Title VI) of the Senate Bill. Similar provisions appear in Sections 1156, 1451, and 1601 to 1654 of the Senate Bill. There is much similarity in these provisions in the two bills; this discussion notes some of the differences.
4. The Stark Law applies to Medicaid indirectly, by prohibiting payment of federal matching funds for Medicaid services provided in violation of the Stark Law. 42 U.S.C. § 1396b(s). Federal matching funds provide roughly two-thirds of Medicaid funding. Surprisingly, not all states have adopted parallel state laws prohibiting physician referrals for Medicaid services if the referral would violate the Stark Law.

5. 42 U.S.C. § 1320a-7b, discussed below.

6. 42 C.F.R. § 411.356(c)(1), (3). A “rural provider” is an entity that furnishes at least 75 percent of its designated health services to residents of a “rural area.” A “rural area” is any area that is not “urban,” as designated by the U.S. Office of Management and Budget. 42 C.F.R. § 412.62. For information on current “metropolitan statistical areas” and other areas considered “urban,” see OMB Bulletin No. 10-02 (Dec. 1, 2009), http://www.whitehouse.gov/omb/assets/bulletins/b10-02.pdf.


8. 42 U.S.C. § 1395nn(d)(2)(B), (3)(B). “Specialty hospitals” were those primarily or exclusively engaged in provision of services to patients with a cardiac condition, patients with an orthopedic condition or patients receiving a surgical procedure. 42 U.S.C. § 1395nn(h)(7).

9. 42 U.S.C. § 1395nn(b)(3), (c), (d)(1); 42 C.F.R. § 411.355(c).


11. The House Bill would require hospitals to meet these conditions as of January 1, 2009. H.R. 3962, Sec. 1156. The Senate Bill originally provided an effective date of February 1, 2010 (H.R. 3590, Sec. 6001), but this date was extended to August 1, 2010, before passage (H.R. 3590, Sec. 10601).

12. In 2004, Physicians’ Hospital (formerly Woodland Park Hospital) in Portland, Oregon was purchased by a group of physician investors. In mid-2005, hospital staff called 911 and had a patient transferred to another area hospital because no physician was on site when the patient’s heart stopped after surgery. Portland Business Journal, Jan. 26, 2007.


15. H.R. 3590, Sec. 6003.


18. H.R. 3590, Sec. 6409; H.R. 3962, Sec. 1621.

19. In this context, “physician” includes MDs, DOs, DDSs, DMDs, podiatrists, optometrists and chiropractors. 42 U.S.C. § 1395x(r).

20. H.R. 3590, Sec. 6002. Under the House Bill, payments or transfers by all distributors, not just those under common ownership with a manufacturer, would also have to be reported. H.R. 3962, Sec. 1451.


22. The “covered recipients” under the House Bill also include all prescribers of drugs or devices, pharmacists, health plans, hospitals and others. H.R. 3962, Sec. 1451.

23. Section 6004 of the Senate Bill requires drug manufacturers and distributors to report the type and quantity of drug samples distributed to practitioners each year beginning with 2011 (reporting in April 2012). The House Bill calls for reporting of drug samples, but provides that the information is not generally available to the public. H.R. 3962, Sec. 1451.

24. 2011 under the House Bill. H.R. 3962, Sec. 1451.

25. The House Bill allows delay only until the clinical investigation is registered on the National Institutes of Health web site or two years after payment, whichever is earlier. H.R. 3962, Sec. 1451.

26. H.R. 3590, Sec. 6402.

27. E.g., Hanslester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995); compare, United States v. Sparks, 157 F.3d 833, 838 (11th Cir. 1998).

28. H.R. 3590, Sec. 6401; H.R. 3962, Sec. 1631.

29. A fee of $200 for individual providers was removed before passage. H.R. 3590, Secs. 6401, 10603.

30. See 42 USC § 1396a(68) with respect to requirements applicable to participants in Medicaid programs.


33. H.R. 3590, Sec. 6401.

34. H.R. 3590, Sec. 6402; H.R. 3962, Sec. 1641.

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