

The Doctor's Chart

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HCFA Issues First of Two Parts of Final Stark II Rule, Restrictions

The Health Care Financing Administration (HCFA) released on January 3, 2001 the initial portion (Phase I) of the long anticipated final Stark II rule, "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships." In commenting on the new rule, a HCFA press release noted "In general, we have interpreted the prohibition narrowly and the exceptions broadly." Phase I, which represents about 85% of the final rule, can be found in the January 4 *Federal Register*.

The physician referral laws, which are found in § 1877 of the Social Security Act and are commonly known by the name of their primary sponsor, California Congressman Fortney "Pete" Stark, govern physician referrals under the Medicare program to entities or persons with which the physician or a member of his immediate family has a financial relationship.

In giving his approval to the regulations, Representative Stark

noted, "The new regulations are a major improvement over earlier proposals. They protect patients and taxpayers while greatly reducing the hassle to providers. As the Justice Department and HHS Inspector General have said, this law has saved the public hundreds of millions of dollars—I would say billions—and prevented patient abuse. Ethical providers will have no trouble complying with these new regulations."

The Stark I law, which became effective in 1992, rendered it illegal for physicians to refer Medicare patients to clinical laboratories with which they, or members of their immediate family, have a financial relationship. Stark II, which went into effect in 1995, augmented the scope of the original law by extending

the prohibition on self-referrals to include physician referrals of Medicare and Medicaid patients for any of 11 "designated health services (DHS)," including X-rays, chemotherapy drugs, and physical therapy, unless one of several statutorily-defined exceptions is applicable.

HCFA initially released proposed regulations for Stark II in January 1998. However, after receiving a large number of public comments (HCFA notes that it received 12,800 responses), a substantial portion of which consisted of criticism from the health care community, the agency responded with a promise to issue significantly revised regulations in June 2000.

This date was ultimately pushed back further, largely due to the complexity of the issues involved. With the exception of one provision in the new Phase I rule, relating to referrals to home health agencies, and which is to go into effect 30 days

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Take precautions, be extra careful, and always act reasonably

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after the date of publication in the *Federal Register*, the effective date for the new rule has been delayed one year. Postponing this date until January 4, 2002 is a consequence of the same complexity that resulted in delayed regulations in the first place.

Phase I of the final rule, which HCFA describes as addressing “a majority” of the Medicare-related issues raised by public responses during the initial comment period, and which is itself open to public comment for 90 days, interprets paragraphs (a), (b), and (h) of § 1877. Paragraph (a) embodies Stark’s general referral prohibition, paragraph (b) describes exceptions to the general rule that apply to both ownership and compensation relationships, and paragraph (h) sets forth almost all of the definitions that are used throughout § 1877, including the group practice definition and the definitions for each of the DHS.

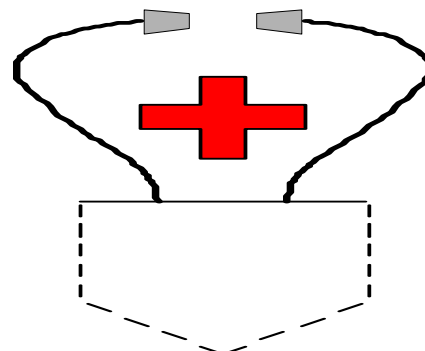
The crux of these regulations is an attempt to strike a workable balance between restrictions on referrals that may lead to abuse, while refraining, as much as possible, from creating undue inconveniences and obstacles to effective treatment. This trend is seen by considering HCFA’s new approach as to what constitutes an “indirect financial relationship” of the sort prohibited by Stark. Whereas under the earlier version of the rule the question of whether the offending entity had knowledge of an

indirect financial relationship with the referring physician would have been irrelevant in determining the propriety of a particular claim, the new rule requires actual knowledge of such a relationship for a Stark violation on this basis to be found. Thus, a referral will not be prohibited unless the following conditions are met: (1) the entity had, or reasonably should have had, actual knowledge of its indirect financial relationship with the physician; (2) the physician’s compensation takes into account the volume or value of referrals generated for the furnishing entity; and (3) there is an unbroken chain of financial relationships between the physician and the entity. The upshot of this language is a significant reduction in the potential liability of entities providing DHS, as long as they can show that they neither knew, nor should have known, of any indirect financial relationship with the referring physician.

Although a complete discussion of the regulatory changes entailed by the recently disseminated rule is beyond the scope of these remarks, certain alterations warrant immediate comment. There is, for instance, an important modification to the ancillary service exception to the general ownership and compensation arrangement rule, which allows physicians to refer DHS within their own practices, provided certain location, supervision, and billing requirements are satisfied. Whereas HCFA had originally proposed that the direct supervision

requirement to this exception necessitates the presence of a physician in the office at the time a DHS was being provided, the Phase I rule interprets the supervision requirement as the same level of supervision that would already apply under all other Medicare payment and coverage rules for the specific service. Moreover, in another departure from the proposed rule, the Phase I rule will allow independent contractors to supervise these services. Therefore, practices that meet the HCFA reimbursement rules for clinical staff supervision will conform with Stark in this respect.

HCFA has also employed the Phase I rule as a device with which to set forth more precise definitions of DHS. Through the use of Current Procedural Terminology (CPT) codes and HCFA Common Procedure Coding System (HCPCS) codes, HCFA has sought to provide a better understanding of which services are encompassed by the DHS label. This decision was made in response to a number of comments generated by the proposed rule to the



News from the Seventh Circuit

Medicare/Medicaid Fraud Convictions Upheld

The Seventh Circuit has been busy in other areas of healthcare law as well, recently handing down two decisions in which it affirmed federal court fraud convictions, one from Illinois and the other from Indiana. In the first case, *United States v. Freitag*, the court affirmed the conviction of Georgia Freitag, the owner of an ambulance company, for defrauding the federal government of more than \$500,000 through the submission of false claims. And in the second case, *United States v. Duncan*, the appellate court affirmed the conviction of the owner of Home Care Connection (HCC), a home healthcare supply company, for defrauding Medicare and Medicaid.

Freitag's appeal stemmed from a guilty verdict in the U.S. District Court for the Northern District of Illinois, where she had been convicted on eight counts of mail fraud, seven counts of making false claims, and one count of healthcare fraud. The charges were based on allegations that Freitag had submitted false reimbursement claims to Medicare for the transportation of a number of Medicare beneficiaries. Although Freitag had been reimbursed for what she claimed to be medically necessary ambulance services, her company in actuality only provided transportation for nursing home residents to their scheduled doctor appointments, along with other non-life supporting services. Freitag's sentence included, among other things, a 41-month term of imprisonment and restitution in the amount of \$507,000.

Freitag appealed her conviction on a number of grounds, including a claim that the district court erred in refusing to excuse a juror who had slept through portions of the trial. Noting that there was no indication that Freitag had been deprived of due process or a fair trial, and that the trial judge had not found an extensive sleeping problem on the part of the juror in question, the appellate court found no merit in this argument and accordingly affirmed the conviction.

The Seventh Circuit's second decision concerned the conviction in Indiana federal court of Elena S. Duncan, the owner and operator of HCC, on four counts of mail fraud. The underlying offenses were committed through the billing of Medicare and Medicaid for certain supplies that were neither ordered nor received by patients, nor prescribed by their doctors. Duncan had evidently instructed her employees to add skin barriers, a form of bandage, to all patient orders. As both Medicare and Medicaid reimbursement of skin barrier purchases is limited to their use in ostomies, ileoileostomies, or colostomies, Duncan's actions were found to constitute fraud. For these offenses, Duncan was sentenced to 52 months in prison.

Duncan contended on appeal that the district court erred in its calculations of the total amount of fraud that she had committed. She specifically argued that Medicaid investigators had counted certain instances of overbilling twice, and that both Medicare and Medicaid investigators had improperly included billings for skin barriers that were warranted by physicians' orders. These arguments were rejected by the Seventh Circuit, which noted that Duncan had offered no evidence in support of either claim.



Wisconsin Suit Against DHHS Organ Transplant Rules Dismissed

A lawsuit brought in federal court by the state of Wisconsin challenging the most recent organ donation rules to be promulgated by the Department of Health and Human Services (HHS) was dismissed on November 22. In dismissing, U.S. District Judge Barbara Crabb noted that none of the plaintiffs, including the state and several transplant hospitals, had suffered an actual injury.

The goal of the challenged rules, originally set forth by HHS Secretary Donna Shalala in 1998, was to establish a more equitable system of organ donation. HHS, which directs the transplant network run under contract by the United Network for Organ Sharing (UNOS), implemented a policy whereby preference was to be given to those patients with the severest illnesses. Given that Wisconsin has a high organ donation rate, and that the 1998 rule poses a perceived risk that organs harvested in this state will now be shipped elsewhere, state officials took umbrage with the new rule. Officials are deciding whether or not to appeal.

HOME HEALTH PHYSICIAN INDICTED FOR MEDICARE FRAUD, \$1 MILLION FORFEITURE SOUGHT BY GRAND JURY

On November 30 a federal grand jury in Illinois indicted Dr. Krishnaswami Sriram on 20 counts of fraud, seeking \$1 million for allegedly defrauding Medicare and other insurance providers by submitting false medical insurance claims and failing to provide services to patients. Specifically, Dr. Sriram was indicted for 10 counts of health care fraud and 10 counts of mail fraud.

The indictment claimed that Dr. Sriram, the owner and operator of Home Doctors, an in-home medical service in Lake Forest, Illinois, submitted claims that he provided certain services, including home visits and inpatient hospital services, which, in fact, he never carried out. Moreover, Dr. Sriram allegedly overstated his bills by claiming that he provided services of a more intricate nature than those that were actually performed.

Also included in the indictment are allegations that Dr. Sriram hospitalized certain patients, despite being aware that such care was not necessary; that he submitted Medicare reimbursement claims for at least 150 dates of service indicating that he worked more than 24 hours in one day; and that he sought reimbursement for providing inpatient hospital services to the same patient at two different hospitals on the same day and for performing certain services to patients after they had passed away.

Each count of fraud, both mail and health care, poses a maximum penalty of five years in prison and a \$250,000 fine.

CLARIFICATION OF “ASSISTANT AT SURGERY” BILLING ISSUE, OTHER ITEMS

HCFA’s November 21 program memorandum has provided much-needed clarity to a billing issue that has drawn amplified scrutiny from federal prosecutors as of late. Indeed, false claims for “assistant at surgery” services drew the ire of DOJ earlier this year, and resulted in a \$500,000 settlement with a Newark, New Jersey cardiovascular and thoracic surgery practice for allegedly overstating services provided by assistant surgeons.

HCFA’s memo, however, has hopefully dispelled some ambiguity on this point. The agency’s latest effort in this regard indicates, “An assistant at surgery must actively assist when a physician performs a Medicare covered surgical procedure.” This essentially means that a proper claim for “assistant at surgery” must entail participation on the part of the assistant in the procedure’s “actual performance,” not merely involvement in other, tangential services.

Moreover, HCFA’s requirement of participation in the surgery itself clearly implies that an assistant cannot bill for another surgical procedure during the time period in which the first procedure is taking place.

The memorandum also discusses the use of observation care codes, offering some direction in that area, and notes that non-physician practitioners can bill for care plan oversight in some circumstances.

Record \$1.5 Billion Recovered in Civil Fraud Cases in 2000

Noting that healthcare fraud cases were its largest source of recoveries, accounting for more than half of the total amount brought in, the Department of Justice (DOJ) announced on November 2 that it received a record \$1.5 billion in civil fraud cases during the past year. This amount shattered the previous record, which was set in 1997, exceeding that mark by almost 50%. Recoveries in healthcare fraud cases amounted to \$840 million of the total, the department reported.

Included in the \$840 million garnered from the health care industry were the following recoveries:

- In a settlement stemming from allegations of fraud by the kidney dialysis subsidiary of Fresenius Medical Care, DOJ received \$385 million, an amount constituting the largest civil fraud recovery in American history;
- \$170 million from Beverly Enterprises, Inc., the largest operator of nursing homes in the United States, for alleged false billings to Medicare;
- In resolving claims against Anthem Blue Cross and Blue Shield, the former Medicare Part A intermediary for Connecticut, for the alleged under reporting of interim payments by hospitals to improve scores on HCFA evaluations, DOJ took in \$74 million; and
- In resolution of claims of fraudulent Medicare billing for unnecessary laboratory tests by Gambro Healthcare Patient Services, Inc., the receipt of \$53 million by DOJ.

Qui tam cases constituted a major portion of DOJ's recovery total, with three quarters of the judgments and settlements, about \$1.2 billion, deriving therefrom. In 2000 DOJ paid whistle blowers \$173 million of the total amount recovered.

Although healthcare cases were by far the most substantial source of recovery, other areas of fraud in which significant recoveries were procured include the following: \$230 million in settlements of oil and mineral production cases, \$140 million in brokerage firm settlements, and \$100 million in settlements for defense procurement fraud.

Waiver of Copays, Deductibles Doesn't Have To Spell Insecurity

Although a physician's decision to waive the co-pay that a patient would typically be required to make runs certain risks, doing so does not have to be as perilous as some industry observers consider it to be. While an increasing number of providers have chosen to forego these waivers, and thus their incumbent risks, it remains acceptable to grant waivers to patients in financial need. Doing so, of course, entails the inestimable benefit of helping the community and disadvantaged patients.

Fortunately, OIG's model plan for small group and individual practices sets forth guidelines for waivers. Included in these parameters is an unambiguous OIG preference for waiving the entire fee, rather than billing "insurance only." Moreover, OIG has made it clear that those physicians who waive fees for a referral source or the family of a referral source will be looked upon with a heightened degree of scrutiny. And it is of course necessary that the decision to waive be based solely on the financial need of the person in question.

The following guidelines offer certain steps that can be taken to provide support for a decision in favor of a waiver:

- Conduct an audit of past decisions to waive fees. This will allow providers the opportunity to discover waivers that might be more difficult to defend.
- It is essential that providers document efforts made to collect debts. Waivers are justified if a debt is uncollectable and must be written off. The standard for a reasonable collection effort requires providers to mail three statements and make a documented phone call. To ensure conformance with the latter requirement, the provider should document who called, the person with whom they spoke, and the response that was generated.
- Since financial need is a prerequisite for a waiver, well documented statements of need can dissuade authorities from focusing on a provider's decisions. Both patient expenses and income should be checked for accuracy. Providers should consider asking patients to supply W-2 forms, along with proof of Social Security benefits and interest income.
- Providers should ensure that policies are instituted whereby only a limited number of individuals have authority to grant approval for waivers.
- Providers should make sure to select a clear standard of poverty and to update it when necessary. Federal poverty guidelines, which are located at <http://www.aspe.hhs.gov/poverty/00poverty.htm>, are a good place to start. Adhering to federal standards will afford an extra layer of security.

Half of Physicians Surveyed Report Retrospective Denials by MCOs Last Year

The Division of Market Research and Analysis of the AMA released a report on December 3 in which one-half of responding physicians indicated that they had retrospectively been denied service claims by managed care plans within the past year. Physicians responding in the affirmative stated that between one percent and three percent of their claims had been denied during this time period.

The AMA report, *Physicians' Experience with Retrospective Denial of Payment and Downcoding by Managed Care Plans*, also noted that 29 percent of those responding said that between 10 percent and 19 percent of their claims had been denied retrospectively during the past year, and that 13 percent of the respondents said that 20 percent or more of their claims were denied retrospectively during this period.

The report indicated that 27 percent of the denials were based on a decision by the managed care plan that the service in question was not covered, 22 percent were based on a lack of prior authorization for the service, and 12 percent of the service denials came from errors in coding.

The report further suggested that certain steps be taken by the AMA to address this problem. The AMA, among other things, should:

- Support legislation that would preclude, in the absence of fraud and/or the use of incorrect information, the retrospective denial of payment for any claims for services for which a physician had obtained prior authorization;
- Cooperate with accreditation groups in the private sector so as to see that the accreditation standards employed by those organizations include appropriate means by which retrospective review can be fairly and accurately effected;
- Act in cooperation with state and local medical associations in an effort to craft strategies for assisting physicians who experience significant percentages of their claims being retrospectively denied; and
- Seek to require, in the case of retrospective denial, that the patient and physician be provided with timely notification, in writing, of the reasons for the decision, along with a description of the appeals process.

A Bankrupt HMO Doesn't Have To Mean a Bankrupt Physician

Physicians all too often find themselves suffering financially when their insurers go bankrupt. The reason for this is simple: if the entity responsible for paying for the care provided by a practice runs out of money, and thus stops making payments, the practice may find itself with a severe cash flow crisis.

This difficulty is compounded by several other factors unique to the field of medicine. For one thing, unlike other professions, where a lack of payment can and does translate to an automatic cessation of service, the ethical and professional obligations inherent in the practice of medicine prevent doctors from halting the treatment of their patients simply because a health plan has ceased making the requisite payments. Moreover, a number of states have imposed laws whereby physicians must continue to provide

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care until a particular course of treatment is completed, regardless of their insurers' financial travails. Nevertheless, while doctors may have scant options after their payors have incurred a fiscal catastrophe, there are certain preventive steps that can be undertaken early on in the provider-payor relationship to offer some semblance of protection.

Physicians, largely due to a diminished view of their own bargaining power, have traditionally been wary of attempting to negotiate favorable terms with their insurers. This tendency, however, is becoming increasingly infrequent, principally as a result of an enhanced awareness among physicians as to the disastrous consequences that can befall them as a result of a financial calamity on the part of their payor. So, what can be done? The following checklist provides a basic starting point:

- Before entering into negotiations, practices should seek to have potential payors disclose pertinent financial data. Updates should be sought every time the option for renewal arises. This will provide doctors with an ongoing appraisal of their insurers' finances.
- Physicians should seek the inclusion of contractual provisions that ensure their protection in the event that the Plan pays late, fails to pay, or folds altogether. An example of one such term would be a device whereby the physician has the right to terminate the contract if the Plan ceases making payments in a timely manner. Another possibility is a provision that would afford the practice, in the event the Plan fails to make payments on time, the option of refusing to accept Plan enrollees as patients.
- Assurance should be given that where practices, notwithstanding the arrears of their insurers, continue to provide patient care, the latter remains responsible for the cost of that additional care.
- Physicians should consider negotiating for an escrow or bond as a guarantee of payment.
- Practices should be wary of plans that tend to extend their payment deadlines. Although larger insurers, as a result of the unavoidable delays associated with bureaucracies sometimes move at a slower pace, physicians should remember that even the slightest hold up can be a warning sign that a Plan is in financial trouble.

Income Guarantees May Pose Kickback Problem, OIG Says

The Department of Health and Human Services Office of Inspector General (OIG) has expressed concern that certain physician recruitment and retention perks might violate federal anti-kickback laws.

Final compliance guidelines issued by the OIG outlines risks posed by incentive arrangements. In its guidelines the OIG identified certain illegal practices frequently involved in physician recruitment and retention efforts, noting that occasionally incentives are actually kickbacks "to obtain and increase patient referrals from physicians." Four instances of "questionable incentive arrangements" are put forth by the OIG:

- Provision of free or significantly discounted billing, nursing, or other staff services;
- Payment of a physician's travel costs and expenses for conferences;
- Payment for a physician's services that require few, if any, substantive dues; and
- Guarantees that if the physician's income fails to reach a predetermined level, the entity will supplement the remainder up to a certain amount.

The safe harbor to the Anti-Kickback statute, which offers potential protection to a specific set of incentive arrangements, was not discussed in the OIG's guidelines. Although this provision protects payments for certain costs for up to three years after a physician relocates, its requirements are exceedingly narrow in scope.

Clinton, Shalala Issue Final Privacy Rule Pursuant to HIPAA Mandate



On December 20, 2000, at a ceremony at the Department of Health and Human Services headquarters in Washington, President Clinton and Secretary Shalala announced the issuance of comprehensive federal protections for the privacy of personal health information. The final regulations, which were published in the December 28, 2000 *Federal Register*, will be fully implemented within two years and were issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

In releasing the new rule, President Clinton remarked, “the new rules . . . protect the medical records of virtually every American. They represent the most sweeping privacy protections ever written.” Noting the prevalence today of storing medical information electronically, the President pointed out that the final rules “have been carefully crafted for this new era, to make medical records easier to see for those who should see them, and much harder to see for those who shouldn’t.”

Recognizing the need for national patient record privacy standards, HIPAA’s bipartisan drafters gave Congress until August 21, 1999 to enact comprehensive health privacy legislation. Following three years of fruitless legislative meandering on this matter, HIPAA granted HHS the authority to create the mandated protections via the rulemaking process. Basing its design on the recommendations set forth for national health information privacy legislation that the Clinton Administration submitted to Congress in 1997, HHS drafted regulations calculated to afford certain protections to patients and to guard against the disclosure or misuse of patient records. These proposed regulations, which Shalala released in October 1999, received more than 52,000 public comments.

The final regulations, which cover health plans, health care clearinghouses, and healthcare providers who transmit health data electronically,

include several important differences from those proposed in 1999. For one thing, the scope of information protected in the final version is more expansive than it originally had been. Under the final rule all medical records and other individually identifiable health information held or disclosed by a covered entity in any form, whether communicated electronically, orally, or on paper, will be protected. Under the original proposal, however, protection would have been given solely to electronic records and to paper records that had at some point existed in electronic form. Thus, under the new rule a zone of privacy has been created that encompasses almost all healthcare information held by hospitals, health plans, health insurers, and healthcare providers.

Another important change concerns the disclosure of patient information. Under the final regulations, most providers are required to obtain patient consent for the routine disclosure of health records. Recognizing the clear necessity of encouraging the unhindered transmittal of detailed patient information among providers for purposes of treatment, the rules grant healthcare providers full discretion in determining what to include in such exchanges. With most disclosures, however, such as information related to billing, covered entities are required to send only the minimum information needed for the purpose of the disclosure. Moreover, where non-routine disclosures are sought, as in the case of marketing or fund-raising efforts, special patient authorization must be procured. This shift represents a dramatic reversal from the proposed rules, which would have allowed routine disclosures without advance consent for purposes of treatment, payment and health care operations. Furthermore, the protections afforded by this consent requirement are augmented by the inclusion of a provision whereby patients are to be given a detailed written explanation of their privacy rights and how their personal data can and will be used, stored, and disclosed.

Finally, the new rules add a

degree of clarity to a set of workplace privacy safeguards that had originally been included in the proposed regulations. The decision to more precisely delineate HHS’s policy in this respect was a direct consequence of the opportunity for comment generally entailed in the rulemaking process. Indeed, HHS received numerous comments to the effect that its proposed rule did not clearly explain its limits on employers access to personal health information for purposes unrelated to health care without consent. Under the final rules, without patient authorization, employers that sponsor ERISA covered health plans will not be able to access the personal information held by the Plan for employment related purposes.

Other important provisions of the new HIPAA regulations include the following:

- Patients will have the right to view, and make copies of, their own records, as well as the right to request the correction of errors in their files. Moreover, health plans and providers are required to inform patients as to the manner in which their personal information is being used and to whom it has been disclosed. Patients are guaranteed a disclosure history, which must be provided within 60 days of the date on which it is requested, and which must list the entities that received information unrelated to treatment or payment.
- Covered entities must establish internal procedures for the purpose of protecting the privacy of health records. Designed to strike a balance between ensuring that certain safeguards are implemented, while taking account of each entities’ unique characteristics and not stifling ingenuity through the imposition of oppressively detailed require-

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ments, the regulations set forth clear goals, while leaving the issue of means up to the entities covered. The mandatory procedures include: adopting written privacy procedures detailing with who has access to protected information and when it can be disclosed; training employees to understand the new protections; designating a “privacy officer” to ensure compliance; and establishing grievance procedures for patients.

Although the final rule does not expressly give patients a private right of action, Peter P. Swire, White House Office of Management and Budget Chief Counselor For Privacy, has suggested that the regulation may provide a standard of care that patients could use in state courts. HHS had initially proposed that patients be listed as third-party contract beneficiaries, but this provision was ultimately withdrawn.

Nevertheless, the rule includes both civil and criminal penalties. Health plans, providers, and clearinghouses that violate the new standards may face civil penalties of \$100 per person for unintentional disclosures and other violations up to \$25,000 per person, per year. Covered entities that knowingly and improperly disclose or obtain information under false pretenses may face criminal penalties, with more onerous consequences for entities that transgress HIPAA intentionally in an effort to benefit themselves financially. Available sanctions include: fines up to \$50,000 and up to one year in prison for obtaining or disclosing protected information; fines up to \$100,000 and up to five years in prison for obtaining similar information under false pretenses; and fines up to \$250,000 and up to 10 years in prison for obtaining or disclosing protected information with the intent to sell for financial gain. HHS Office for Civil Rights will be in charge of enforcement.

The final rule, which applies equally to the public and private sector, is projected to cost \$18 billion over ten years. However, when viewed in light of the projected ten year \$30 billion savings for the recently released electronic claims

regulation, the net effect of the two sets of HIPAA regulations is savings of approximately \$12 billion over ten years. These savings, moreover, are to be accrued against a backdrop of improved efficiency and enhanced privacy protections in the health care delivery system.

The new regulation is available for perusal at the following address: <http://www.aspe.hhs.gov/admsimp/>.

New Medicaid Managed Care Rule Includes Patient Protections

HCFA published on January 19 a new rule designed to give states more flexibility in administering Medicaid managed care provisions. In a press release, HHS noted that the regulations, which will provide greater protections to Americans enrolled in public health care programs, fulfill a promise made by President Clinton to extend a Patients’ Bill of Rights to patients in such programs. The rule implements provisions of the Balanced Budget Act of 1997 and becomes effective on April 19.

In commenting on the new rule, HHS Secretary Shalala remarked that while “Managed care provides the promise of better coordinated health care at a more reasonable cost . . . all Americans—whether they are in Medicare, Medicaid, or private health plans—deserve the basic protections that a Patients’ Bill of Rights provides.” The regulations reflect HCFA’s response to the more than 300 comments it received after rules were originally proposed in September 1998.

The new rules include a number of patient protections. HCFA will henceforth require managed care plans that serve Medicaid beneficiaries to provide consumers with understandable, yet comprehensive, information about how their plans operate. The names of participating providers, along with contact information, must be included. In states where Medicaid managed care is mandatory, beneficiaries must be offered a choice of at least two such plans.

Also incorporated in the new regulations are protections for individuals who have special healthcare needs. States will now have to guarantee continued healthcare access to such individuals who

transfer from fee-for-service care to managed care plans, between health plans, and from a health plan to fee-for-service care. Moreover, states and health plans will hereafter be required to identify enrollees who have special healthcare needs and to evaluate the quality and appropriateness of their care.

Furthermore, the rule prescribes that mandatory screening and assessment take place for all enrollees within a delineated period of time. Shorter time frames are to be used for those patients who are identified as having special healthcare needs, along with those at risk of having such needs.

The new rule also mandates that managed care plans cover the cost of emergency healthcare services wherever and whenever the need for such services arises, thereby providing another layer of patient protection. The use of a prudent lay person standard will determine whether these services are warranted, requiring payment in instances where the beneficiary reasonably believes that he or she is in an emergency situation. The regulations preclude plans from insisting upon prior approval for emergency services or that patients obtain such services only at designated facilities.

In one major change from the proposed rule, the new regulations establish specific requirements for state rate setting. This facet of the regulations is meant to ensure that all managed care capitation rates are actuarially sound. As the former regulatory ceilings on what states were allowed to pay managed care plans were generally considered to be out of date, this is an important shift. Since this provision entails a new approach to regulating capitation payments, comments hereon will be accepted through March 20.

Finally, the regulation contains a number of other patient protections, including increased access to services; prohibitions on establishing restrictions that inter-

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ere with patient-provider communications; mandatory state approval of the marketing of managed care plans to enroll Medicaid beneficiaries; prohibitions on certain marketing activities; implementation of a grievance and appeal system, operating under certain time frames; and new health plan quality performance standards to be usedn by the states.

The rule, available in the Federal Register, can be located at: http://www.access.gpo.gov/su_docs/fedreg/a010119c.html.

OUR NEWSLETTER is designed to provide you with highlights of recent health care issues. Because the articles are general in nature, we encourage you to contact your attorney for personal advice before you act. If you would like to retain our services, call (920) 339-6377.

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