CCH Health Care Compliance LETTER

Volume 8, Issue 22 health.cch.com November 3, 2005

On The Front Lines 4

Stark law, Anti-kickback Statute, and CMP law issues in gainsharing by Paul Danello, J.D.

Fraud and Abuse 1

- Safe harbors and exceptions for technology proposed
- Proposed donation of building to school not subject to sanctions
- ALJ cites higher prices in hospital sale order

Trends 3

- Senate committee approves antitrust investigations bill
- Senator Grassley calls on nonprofit hospitals to develop policies
- Identity theft amendment could protect Medicare beneficiaries
- Proposed arrangement to provide free supplies to physicians not within safe harbor
- Senate Finance Committee approves deep cuts to Medicare, Medicaid

Submission of Articles. Requests for information about article submission guidelines should be sent directly to Andra Popa at andra.popa@wolterskluwer.com.

For more information about the CCH Health Care Compliance Portfolio, please visit our online store at http://health.cch.com.

Safe harbors and exceptions for technology proposed

by Andra Popa, J.D., LL.M

Hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations that provide specified recipients hardware, software, or information technology and training services that are necessary and used solely to receive and transmit electronic prescription drug information would be eligible for new safe harbors under the federal Anti-kickback Statute and exceptions under the Stark law pursuant to two proposed rules. In addition, safe harbors and exceptions related to electronic health records would also be adopted.

Requirements for protected technology. Under the electronic prescribing technology safe harbor and exception, protected items and services would be required to be used only to transmit or receive electronic prescribing information. Items used only occasionally for electronic prescribing would not be protected. Pursuant to the safe harbors related to electronic health records, the "pre-interoperability" safe harbor would protect electronic health records software and directly-related training services, provided that the software includes an electronic prescribing component. Moreover, the "post-interoperability" safe harbor would include an electronic prescribing component and would assure that recipients do not use the technology protected under this section solely to conduct personal business or business unrelated to their medical practice. Similarly, the Stark exception particularly applies to items and services that are part of interoperable systems, or systems that exchange information between providers and certain entities.

Requirements for donors. Donors of the software or hardware would be limited to hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations under the safe harbors and the exceptions. Donors would not be permitted under the federal Anti-kickback Statute to bundle software for general office management, billing, scheduling, or other software with the electronic prescribing features if any purpose of the software packaging were to induce referrals. Under both the Stark laws and the Anti-kickback Statute, the donor would not be able to take any actions to disable or limit the interoperability of the software or the hardware. This condition limits the ability of donors to use electronic prescribing technology to bind the recipient to the donor.

Requirements for recipients. Recipients would be restricted to prescribing health care professionals, pharmacies, and pharmacists under both the safe harbors and the exceptions. The safe harbors would require recipients to certify that items and services provided by a donor do not technically or functionally duplicate the technology that recipients currently have or have obtained. The electronic prescription drug safe harbors and

continued on page 2

exceptions would fulfill the requirements of the Medicare Modernization Act (MMA) (see PubLNo 108-173) requirement that standards must be adopted for electronic prescribing in connection with the new prescription drug benefit and that an exception must be created to the Anti-kickback Statute to protect arrangements involving the donation of electronic prescribing technology. The safe harbors and exceptions related to electronic health record software and training services are permitted under a separate legal authority created by the MMA. Comments to the proposed rules must be received by December 12, 2005. ■

Proposed Rule, 70 FR 59015, Oct. 11, 2005, ¶730,004; Proposed Rule, 70 FR 59182, Oct. 11, 2005, ¶730,003.

Proposed donation of building to school not subject to sanctions

by Gene' Stephens, J.D., Contributing Editor

A proposed donation of a medical building to an affiliated state university by a hospital would not subject the hospital or university to administrative sanctions under the Anti-kickback Statute because the arrangement consists of a one-time donation that confers a community benefit to federal health care patients, most of whom are either Medicaid beneficiaries or uninsured.

In addition, the proposed donation will allow the university to maintain a clinic for patients to receive services at a conveniently located facility, as well as provided faster access to emergency medical care. The donated facility also would improve the training of medical residents in the university's residency program.

The hospital further certified that its teaching physicians and other affiliated physicians would not:

- require or encourage university physicians to refer patients to the hospital or any other institution;
- track referrals made by university physicians to the hospital or any other institution;
- relate the compensation paid to university physicians to the volume or value of referrals by such physicians; or
- provide the university with free below market value goods or services that were directly or indirectly related to the building.

Finally, the hospital asserted that it would not be involved in any decisions related to the nature of services offered by the clinic or any other decisions related to the donated building. ■

> **"The arrangement consists of a one-time donation that confers a community benefit to federal health care patients, most of whom are either Medicaid beneficiaries or uninsured."**

OIG Advisory Opinion, Aug. 9, 2005, ¶ 500,134.

ALJ cites higher prices in hospital sale order

Andra Popa, J.D., LL.M

In an initial decision, an administrative law judge (ALJ) determined that a hospital corporation used market power obtained through the acquisition of a hospital to obtain price increases. The ALJ ordered the corporation to divest of the hospital to a buyer approved by the Federal Trade Commission (FTC) in a manner approved by the FTC.

The decision arose from an administrative complaint issued by the FTC in February 2004 alleged that the hospital corporation's acquisition of a hospital resulted in "substantially lessened competition" and higher prices for insurers and healthcare consumers for general acute inpatient services sold to managed care organizations in the geographic market defined by the ALJ. The ALJ upheld Count I of the FTC's complaint, which alleged that the merger of a hospital corporation with a separate hospital substantially lessened competition in the relevant market, resulting in the violation of antitrust law. The ALJ explained that evidence collected during and after the acquisition demonstrated that the hospital corporation used its post-merger market power to obtain price increases significantly above the prices it charged before the merger. The ALJ also found that the corporation was able to increase prices by a substantially larger amount as compared to its competitors. The ALJ also noted that after the merger in 2002 and 2003, the corporation continued to raise rates and

Portfolio Managing Editor
Pamela K. Carron, J.D., LL.M

Coordinating Editors
Susan Smith, J.D., M.A.
Andra Popa, J.D., LL.M

CCH Washington Bureau
Paula Cruickshank
DOJ, FTC–John Scorza
SEC–Peter Feltman
Health Law–Catherine Hubbard
Tax–Jeff Carlson, Steve Cooper

Designer
Craig Arritola

Comments from readers are welcome and should be directed to Andra Popa at popaa@cch.com, Tel. 847-267-2476, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

CCH Health Care Compliance Letter is published 24 times a year by CCH INCORPORATED, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A.
All rights reserved. ©2005 CCH INCORPORATED, A WoltersKluwer Company.

No claim is made to original government works; however, the gathering, compilation, and arrangement of such materials, the historical, statutory and other notes and references, as well as commentary and materials in this Product or Publication are subject to CCH's copyright.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting or other professional service. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

Unless otherwise noted, all paragraph references are to the CCH Health Care Compliance Reporter.

"significantly increased the prices paid by managed care organizations for the hospital corporation's services."

The ALJ dismissed Count II as moot. Count III of the complaint, alleging that the corporation's physician group improperly bargained on behalf of its physicians and entered into contracts with health plans and payors was previously settled (see Health Care Compliance Letter, Vol. 8, Issue 9, May 2, 2005, Chicago-area doctors' group settles FTC price fixing charges). ■

In the Matter of Evanston Northwestern Healthcare Corporation, Initial Decision, No. 05-06, Oct. 20, 2005.

Trends

Senate committee approves antitrust investigations bill

by John Scorza, Contributing Editor

The Senate Judiciary Committee on October 20 approved a bill designed to improve the investigation of criminal antitrust offenses. The bill – the Antitrust Criminal Investigative Improvements Act (S. 443) – would add criminal antitrust offenses to the list of offenses that allow the Justice Department to seek a wire-tap order from a federal judge to monitor communications between suspected antitrust conspirators.

Senator Herb Kohl (D-Wis.), a co-sponsor of the legislation, observed upon the bill's introduction, "Because of their secret nature, antitrust conspiracies are extremely hard to uncover unless prosecutors can penetrate the inner workings of the conspiracy. And antitrust conspiracies such as price-fixing and bid-rigging steal from consumers just as surely as other white-collar crimes such as mail or wire fraud for which prosecutors do have the ability to obtain wiretaps. It is vital that we give law enforcement all the necessary tools to detect these conspiracies." Sen. Mike DeWine (D-Ohio) introduced the bill earlier this year. ■

CCH Washington Bureau, Oct. 21, 2005.

CCH ComplianceEdge

CCH and Ernst & Young bring you *ComplianceEdge*, the definitive net-based, interactive healthcare compliance training program to train corporate healthcare professionals on essential compliance topics.

Senator Grassley calls on nonprofit hospitals to develop policies

by Andra Popa, J.D., LL.M, Contributing Editor

Senate Finance Committee (Committee) Chairman Charles Grassley (R-Iowa) stated at the 2005 Independent Sector Annual Conference that the Committee is currently reviewing the responses from the ten tax-exempt hospitals it requested to answer inquiries earlier this year relating to their tax-exempt status (see CCH Health Care Compliance Letter, Vol 8-13, June 27, 2005).

"The answers from the hospitals and other materials received by the Committee show there is little to no common policy among hospitals," Grassley stated. "I anticipate we will write additional letters to those hospitals to seek clarification on the answers provided. We may also write to other hospitals as well as the Health and Human Services Department.

"We're finding that there aren't even common definitions about such critical areas as charity care and community care," Grassley added. He cautioned that "the public must have confidence that the significant tax breaks received by tax-exempt hospitals are balanced by community benefits."

Based on these preliminary findings, Grassley recommended that "the nonprofit hospital community to take a page from the nonprofit panel." "It should come forward with its own substantive proposals for common definitions and reforms in areas such as community benefit, charitable care, charges to the uninsured, debt collection and joint ventures," he advised. ■

Remarks of Senator Charles Grassley, Chairman, Committee on Finance, 2005 Independent Sector Annual Conference, CEO Summit, Monday, Oct. 24, 2005.

CCH Health Care Compliance Editorial Advisory Board

Timothy P. Blanchard, Esq.
McDermott, Will & Emery

Patricia L. Brent, J.D., M.P.H.
President, Morgan Hill Associates

Neil B. Caesar, Esq.
President
The Health Law Center

Paris Cavic, Esq.
Albany, New York

Michael E. Clark
Partner
Hamel Bowers & Clark LLP

Bill Dacey, MBA, MHA, CPC
President
The Dacey Group

Allan P. DeKaye, MBA, FHFMA
DeKaye Consulting, Inc.

Paul R. DeMuro, J.D., MBA
Partner
Latham & Watkins

Louis H. Feuerstein
Corporate Compliance Program National Leader
Ernst & Young

Cynthia Reaves, Esq.
Honigman Miller Schwartz and Cohn

Fay A. Rozovsky, J.D., M.P.H.
Quality Medical Communications, LLC

William P. Schurgin, Esq.
Seyfarth, Shaw, Fairweather & Geraldson

John E. Steiner, Jr., Esq.
Chief Compliance Officer for
Cleveland Clinic Health System

Sanford V. Teplitzky, Esq.
Ober, Kaler, Grimes & Shriver

On The Front Lines

ASPEN PUBLISHERS

Stark law, Anti-kickback statute, and CMP law issues in gainsharing

by Paul Danello, J.D., Health Care Practice, Ropes and Gray

In the last of a series of three excerpts from the 2006 Health Law and Compliance Update, published by Aspen Publishers, Paul Danello provides a detailed analysis of gainsharing and fraud and abuse. In Part III of the series, Mr. Danello focuses on the Anti-kickback Statute and Civil Monetary Penalty Law (CMP Law).

Stark law issues. The Ethics in Patient Referral Act of 1989 (Stark I), as amended by the Omnibus Budget and Reconciliation Act of 1983 (Stark II), called collectively the "Stark Law" (Section 1877 of the Social Security Act), prohibits a physician from making referrals for designated health services, for which payment may be made under the Medicare or Medicaid program to entities with which the physician has a financial relationship, unless the arrangement qualifies for one of the available exceptions. The Stark Law also covers commercial relationship which must meet an exception. This would include a commercial payor arrangement. All financial relationships with physicians, including gainsharing programs, must fit within a specific Stark Law exception, regardless of the parties' intent. Relevant Stark Law exceptions would include:

- Employed Physicians:
  - Bona fide employment exception (42 C.F.R. § 411.357(c).
- Non-Employed Physicians:
  - Personal services arrangements exception (42 C.F.R. § 411.357(d)),
  - FMV compensation exception (42 C.F.R. § 411.357(l)),
  - indirect compensation exception (42 C.F.R. § 411.357(p)), or
  - academic medical center exception (42 C.F.R. § 411.355(e))
  - MCO/Hospital: Risk-sharing arrangements exception (42 C.F.R. § 411.357(n)).

CMS has not yet issued any guidance regarding the application of the Stark Law to gainsharing programs. However, OIG did note in its 1999 SAB and in the Advisory Opinions discussed below that such programs may implicate the Stark Law.

> **"CMS has not yet issued any guidance regarding the application of the Stark Law to gainsharing programs."**

Anti-Kickback Statute issues. The Anti-Kickback Statute (Section 1128B(b) of the Social Security Act) makes it a felony for persons knowingly and willfully to solicit, receive, offer, or pay any remuneration directly or indirectly, overtly or covertly, in cash or in kind, to any person, in return for or to induce such person either to refer patients for Medicare or Medicaid reimbursed services, or to arrange, recommend or order any item or service reimbursed by Medicare or Medicaid. The Anti-Kickback Statute can be implicated in commercial transactions where there are business swapping arrangements with respect to payments made by Medicare and commercial payors.

A gainsharing program may satisfy either a regulatory safe harbor or a facts-and-circumstances test. Relevant Anti-Kickback Statute safe harbors would include:

- Employed Physicians:
  - Employment safe harbor (42 C.F.R. § 1001.952(i))
- Non-employed Physicians:
  - Personal services and management contracts safe harbor (42 C.F.R. § 1001.952(d))
- MCO/Hospital:
  - Managed care organization safe harbor (42 C.F.R. § 1001.952(t))

OIG has set forth its position most recently in its newly-released Supplemental Compliance Program Guidance for Hospitals as follows: "We recognize that, properly structured, gainsharing arrangements can serve legitimate business and medical purposes, such as increasing efficiency, reducing waste, and thereby increasing a hospital's profitability."

Anti-kickback statute is implicated, according to the OIG, if the cost-savings payments are used to influence referrals:

- "Cherry picking" of healthy patients
- "Intent to foster physician loyalty and attract more referrals"
- Overly broad arrangements under which "a physician continues for an extended time to reap the benefits of previously-achieved savings or receives cost-savings payments unrelated to anything done by the physician"

OIG advises: "Whenever possible, hospitals should consider structuring cost-saving arrangements to fit in the per-

sonal services safe harbor." See 42 C.F.R. 1001.952(d). See also the employment safe harbor at 42 C.F.R. 1001.952(i) OIG Advisory Opinions 05-01 to 05-6, Advisory Opinion 01-01, and Advisory Opinion 00-02 note that gainsharing programs may generate prohibited remuneration within the meaning of the Anti-Kickback Statute. Almost all incentive and gainsharing arrangements might be construed as payments for referrals under the Anti-Kickback Statute. Any incentive or gainsharing arrangement analysis must focus on the Anti-Kickback Statute exceptions, statutory and regulatory safe harbors, and the intent of the parties. The question to be answered, usually under a facts-and-circumstances analysis, is whether the arrangement is intended to induce referrals (i.e., the failure to comply with an exception or a safe harbor is not fatal). Note that gainsharing arrangements may not comply with an Anti-Kickback safe harbor even though they may come within a Stark Law exception.

For example, gainsharing arrangements in which the compensation paid to a physician is based on a percentage-of-savings basis are not likely to be deemed to be "set in advance" for purposes of the Anti-Kickback Statute personal services and management contracts safe harbor even though they may come within the Stark Law personal services exception or fair-market-value exception. **Overlap between Anti-Kickback Statute and Civil Monetary Penalties Law.** The civil money penalty provisions of Section 1128A(b)(1) of the Social Security Act (the "CMP Law") prohibits a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's care. Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly known as Medicare+Choice plans) are subject to regulation by the Secretary pursuant to Sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Social Security Act (respectively), in lieu of being subject to the CMP Law.

"It should be borne in mind that compliance with an Anti-Kickback Statute safe harbor does not protect programs from violating the CMP Law."

The CMP Law is an intent-based statute with no safe harbors of its own. It should be borne in mind that compliance with an Anti-Kickback Statute safe harbor does not protect programs from violating the CMP Law. The CMP Law prohibition applies to physicians who have direct patient care responsibilities and extends to inducements to limit any care, not merely medically necessary care. Examples of potentially prohibited incentives include incentives designed to limit or reduce services a hospital would normally provide to a patient, and plans that encourage admission of likely low-cost cases to the hospital while excluding higher-cost patients.

It is possible to structure gainsharing arrangements so as not to violate the CMP Law or the Anti-Kickback Statute. Examples include:

- non-hospital programs,
- programs that exclude Medicare and Medicaid patients,
- programs that apply to non-physicians (or only to physicians who do not have responsibility for direct patient care).
- programs that reward physicians based on quality or patient satisfaction (i.e., programs not relating to the quantity or cost of clinical services).
- programs that are based on a fixed-fee or hourly rate compensation methodology.

1999 OIG Special advisory bulletin. In light of the IRS guidance in its 1999 private letter rulings (see above), many in the industry were originally expecting the issuance of a favorable advisory opinion by the OIG. On July 8, 1999, the OIG released a Special Advisory Bulletin ("SAB") entitled Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries in which it concluded that gainsharing arrangements involving payments to physicians to induce a reduction or limitation of services to Medicare or Medicaid patients are "flatly prohibited" by the CMP Law.

The CMP Law prohibits a hospital from knowingly making a payment, directly or indirectly, to induce a physician to reduce or limit services to federal health care beneficiaries under the physician's direct care. A hospital that makes, and any physician who accepts, such payments is subject to civil money penalties of up to $2,000 for each patient covered by the improper payments. The OIG adopted the position that the prohibitions under the CMP Law apply to any reduction in medical services rather than a reduction in medically necessary services. In contrast, the OIG is generally fond of reminding providers that the Medicare program covers only "medically necessary" services - why would Congress be interested in a reduction of non-necessary services if the overall quality of care is not impacted? According to OIG, a violation may also occur if the hospital knows the payments may induce physicians to reduce or limit services to patients, even if no actual reduction in care occurs.

The OIG based its interpretation of the CMP Law, in part, on the 1986 GAO Report. The 1986 GAO Report concluded that hospital physician incentive plans designed to reduce the length of stay and service intensity for Medicare hospital patients may be subject to abuse. According to the OIG, it was still possible to structure gainsharing arrangements without violating the CMP Law, but any such arrangements must still satisfy the requirements of the Anti-Kickback Statute. An example of such an arrangement would be a personal services contract where a hospital pays

a physician based on a fixed fee (or hourly rate) that is fair market value for services rendered rather than a percentage of cost savings (i.e., potentially avoiding payments intended to induce a limitation in services provided). The OIG expressly declined to issue advisory opinions on gainsharing because: the OIG, to date, has only exercised its discretion to protect arrangements which pose a minimal risk of fraud and abuse, as compared to gainsharing arrangements which pose a serious risk of fraud and abuse in OIG's view, such that it would be "imprudent and inappropriate" to immunize such arrangements from sanctions; the ongoing oversight required for gainsharing programs as to both quality of care and fraud and abuse is not available through the Advisory Opinion process; and case-by-case determinations by Advisory Opinions are an "inadequate and inequitable" substitute for comprehensive and uniform regulation in this area.

The OIG did indicate it would consider revised advisory opinion requests but that providers should ignore the SAB only at their own risk. On August 19, 1999, the OIG released a follow-up letter to the SAB to clarify that hospital-based physician incentive plans limited to Medicare or Medicaid beneficiaries enrolled in risk-based managed care are not subject to the CMP Law, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm.

"Commentators also asserted that OIG ignored its legal duty to issue advisory opinions interpreting the CMP Law in an attempt to ban all gainsharing programs because of lack of staff to review numerous opinion requests. In response, the OIG argued that the CMP Law only requires an intent to induce (not actual reduction or limitation of services), the principal evil being the potential for financial considerations to influence a physician's medical judgment."

OIG Advisory opinions on gainsharing after 1999 special advisory bulletin. The OIG favorably reviewed a proposed cost savings program pursuant to which a hospital would reward its non-physician employees for submitting cost saving suggestions implemented by the hospital. Participation was limited to non-physician employees of the hospital, although some of the participating employees would be in a position to make referrals for, or arrange for the referral or provision of, items or services reimbursable by federal health care programs.

Non-physician employees would submit written cost saving suggestions to the HR department of the hospital. If the hospital determined that the cost saving suggestions were feasible, the employee would be paid a percentage of the cost savings generated by the suggestion. For suggestions resulting in quantifiable and measurable financial savings, the hospital would pay the employee a set percentage of the cost savings derived during the first year the suggestion was implemented. For cost saving suggestions that could not be measured or quantified, the hospital would estimate its savings and pay the employee an amount based upon a predetermined sliding scale, subject to a predetermined threshold cap.

The hospital certified that (i) no payments would be made under the program, either directly or indirectly, to physicians; (ii) the program would not reward or implement suggestions that would reduce or limit health care services provided to patients or impair the quality of care delivered to its patients; (iii) the program would not reward suggestions that identify specific vendors, directly or indirectly; and (iv) the program would not reward or implement suggestions that would shift costs to a federal health care program. The OIG noted that the program would not implicate the CMP prohibition set forth in Section 1128A(b)(1) of the Act because physicians were prohibited from participating, either directly or indirectly, in the program. The OIG concluded that the program was unlikely to implicate the Anti-Kickback Statute.

Further, even if the Anti-Kickback Statute was implicated, payments to bona fide hospital employees may be protected by the employment safe harbor set forth at 42 CFR § 1001.952(i). Thus, the OIG concluded that the hospital's proposed program: (i) would not violate the CMP law (which prohibit financial incentives to reduce or limit items or services); and (ii) could potentially generate prohibited remuneration under the Anti-Kickback Statute, if the requisite intent to induce referrals were present, but that the OIG would not subject the hospital to sanctions arising under the Anti-Kickback Statute in connection with the establishment of the program itself; provided, however, that the OIG's conclusion does not apply to specific payments made by the hospital for specific suggestions. (It should be noted that the OIG has often used the Advisory Opinion process to protect arrangements that "technically" violate the Anti-Kickback Statute or other provisions of the Social Security Act.) ■

Paul F. Danello, Ch. 10, "Analysis of Gainsharing in OIG Advisory Opinions 05-1 to 05-6 and Other Recent OIF and CMS Guidance," 2006 Health Law and Compliance Update, J. Steiner, ed. (Aspen Publishers 2005). Aspen's Health Law and Compliance Update brings you the latest information on emerging issues in health law every year. Each article is authored by an expert in the area and includes analysis of the latest cases and statutes.

Purchaser Information: ©2005, Aspen Publishers, 2006 Health Law and Compliance Update, ISBN 0735553386, $199, Softcover, Annual Editions. To pre-order, please call Aspen Publishers at 1-800-638-8437.

Mr. Danello is an attorney in the health care practice of Ropes & Gray. He was recently responsible for guidance to the nation's entire health care industry on the topic of fraud and abuse laws as a member of a team in the OIG.

Identity theft amendment could protect Medicare beneficiaries

by John Scorza, Contributing Editor

The Senate approved an amendment that would require the secretary of the Health and Human Services Department to prepare and submit to Congress a plan to ensure that Medicare beneficiaries' Social Security numbers are no longer displayed on their Medicare identification cards or on explanations of benefits sent to beneficiaries. The secretary would be required to submit the report to Congress no later than June 30, 2006.

The amendment is designed to protect seniors against identity theft, said Richard Durbin (D-Ill.), the sponsor of the amendment. Durbin noted that "the Federal Government continues to print Social Security numbers on Medicare cards, leaving 40 million seniors with their Social Security numbers in plain sight." The Senate adopted Durbin's amendment to an appropriations bill (H.R. 3010) on October 25. The House in June passed a version of the bill that would instruct the CMS to stop issuing immediately Medicare cards containing Social Security numbers. But the CMS has objected that the House instructions would be impossible to implement immediately. A House-Senate conference will be charged with working out discrepancies between the competing bills. ■

CCH Washington Bureau, Oct. 26, 2005.

Proposed arrangement to provide free supplies to physicians not within safe harbor

CCH Editorial Staff

A safe harbor was not available for a proposed arrangement that would provide both free blood drawing supplied to physicians and pay a per-patient amount for the physicians' collection of blood specimens, since the arrangement would potentially generate prohibited remuneration under the Anti-kickback Statute for which there is not an available safe harbor, as well as potentially generate administrative sanctions under the Social Security Act § 1128(b)(7). Under the provisions of the arrangement, a state laboratory testing service would pay physicians between three and six dollars for each patient receiving a blood draw based on negotiations between the laboratory and the physician. Medicare pays physicians three dollars per patient encounter for blood specimen collection fees. Under 42 C.F.R. §1001.952(d), the proposed arrangement would not fit into a safe harbor because the physicians will be paid on a per patient basis rather than at an aggregate, pre-set compensation that would be consistent with the fair market value for such services in arm's length transactions.

"The proposed arrangement would not fit into a safe harbor because the physicians will be paid on a per patient basis rather than at an aggregate, pre-set compensation that would be consistent with the fair market value for such services in arm's length transactions."

The compensation provided to the physicians under the proposed arrangement would further give rise to an inference that the higher compensation paid to the physicians was an inducement for patient referrals to the laboratory. The laboratory's representation that the proposed arrangement is a reaction to the existing blood draw remuneration arrangements of competitors provides further evidence that the arrangement would give physicians the opportunity to earn a fee that otherwise would be earned by the laboratory absent a patient referral. Finally, the proposed arrangement presents the risk of overutilization and inappropriate higher costs to federal health care programs because the physicians would receive a portion of the laboratory's reimbursement for blood testing. ■

OIG Advisory Opinion, No. 05-06, June 6, 2005¶ 500,134.

Health Law Treatises and Analysis Series now available

CCH INCORPORATED® and Aspen Publishers have joined together to offer you all the latest information regarding health law with the Health Law Treatises and Analysis Series. You'll have electronic access to what you need—getting the information to you quickly and easily.

Titles in the series include:
- Hospital Law Manual
- Hospital Contracts Manual
- Defending and Preventing Health Care Fraud and Abuse Cases: An Attorney's Guide
- Civil False Claims and Qui Tam Actions

For more information or to order, call 1 800 449 9525 or visit health.cch.com.

ASPEN PUBLISHERS

Senate Finance Committee approves deep cuts to Medicare, Medicaid

by John Scorza, Contributing Editor

The Senate Finance Committee signed off on a budget blueprint that would impose a series of cuts to Medicare and Medicaid, resulting in $10 billion in savings over five years. Under the legislation, Medicare savings would total $4.3 billion and Medicaid savings would total $5.7 billion. The committee approved the measure on October 25 by an 11-9 vote along party lines.

Committee Chairman Charles Grassley (R-Iowa) emphasized that the savings will not result in decreased coverage for beneficiaries. "It reduces wasteful and unnecessary spending and directs those savings where they are needed most," Grassley said.

The legislation would result in nearly $5 billion in Medicaid savings over five years from prescription drug payment reforms. These include a new definition of average manufacturer price to reflect discounts and rebates available to retail pharmacies, and a new federal upper limit for payments to states for covered drugs that goes into effect January 1, 2007.

The bill would result in Medicare savings of $4.5 billion over five years through changes to Medicare payment policies that would encourage and reward quality patient care while controlling rising health care costs.

The legislation would tighten Medicaid asset transfer rules and close other loopholes, with an estimated savings of $335 million. It would save more than $500 million through efforts to combat fraud and abuse, including enhanced third-party recovery and state incentives to use the False Claims Act.

In addition to spending cuts, the committee's budget blueprint would improve Medicaid and the State Children's Health Insurance (SCHIP) coverage in several areas. It would allow parents of severely disabled children to work and earn above-poverty wages while maintaining Medicaid benefits. It would provide for money-follows-the-person demonstration projects to increase the use of home and community based services, rather than institutional services.

The committee-approved package includes temporary relief to the Gulf Coast states hit by Hurricane Katrina. It would reimburse states at 100 percent FMAP for any claims paid on behalf of individuals living in those states when the hurricane struck. The cost of this provision would be $1.9 billion.

But committee Democrats objected that the Katrina provision falls far short of what is needed. "The bill does not provide coverage for tens of thousands of evacuees who are ineligible for Medicaid," remarked Sen. Max Baucus, (D-Mont). "It does not help the health-care providers who have given charity care in the aftermath of the hurricane. And it does not relieve the financial plight that the Gulf Coast states, especially Louisiana, face. I am disappointed by these omissions."

Baucus wants to advance a $9 billion bill (S. 1716) that would temporarily expand Medicaid eligibility to Katrina victims. Grassley too wants to move the bill, which he introduced. "I intend to continue working so that we can enact legislation that would direct additional relief to these states," Grassley remarked. But the bill's prospects appear to be poor in a Republican-controlled Congress that is wary of expanding Medicaid.

The bill would result in Medicare savings of $4.5 billion over five years through changes to Medicare payment policies that would encourage and reward quality patient care while controlling rising health care costs. The secretary of the Health and Human Services Department would be charged with developing and implementing value-based purchasing programs for acute-care hospitals, physicians, Medicare Advantage plans, home health agencies and others.

The legislation would achieve $5.4 billion in savings through the repeal of the regional Medicare Advantage PPO stabilization fund, which was established to promote plan entry and retention in the Medicare Advantage program. An additional $6.6 billion in savings would be realized by modifying the risk-adjusted payment system to Medicare Advantage plans.

As with the Medicaid portion of the legislation, the bill would make a number of changes designed to improve care under the Medicare system. Most significantly, at a cost of $10.8 billion a year, all providers under the Medicare Physician Fee Schedule would see a 1 percent payment rate increase instead of a 4.4 percent cut. At a cost of $710 million, the bill would extend the moratorium on therapy caps.

The Finance Committee legislation now goes to the Budget Committee, which will include cost-savings suggestions from other committees. From there, it will proceed to the floor where a number of amendments are likely to be offered. The House is working on its own budget blueprint, which may contain deeper spending cuts. The final House and Senate packages will have to be merged into legislation acceptable to both chambers. ■

CCH Washington Bureau, Oct. 27, 2005.