CCH Health Care Compliance LETTER

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FTC official explains identity theft red flag rule

The "Identity Theft Red Flag Rules" (Rules) impose mandatory compliance with the regulations that require financial institutions or creditors to establish (1) protocols on discrepancies between an address requested in a consumer report and the address in the consumer reporting agency's file, and (2) policies and procedures to assess the validity of a change of address. Most important, however, the Rules require these same financial institutions or creditors to develop and implement a written Identity Theft Prevention Program to detect, prevent, and mitigate identity theft in connection with a covered account. Examples of identity theft red flags include: (1) warning from consumer reporting agencies, (2) suspicious documents, or (3) suspicious personal information. The Rules have been delayed for six months, until May 2009, from an initial implementation date of November 1, 2008.

Regulations. The final rule and regulations were jointly issued on November 9, 2007, by the Federal Trade Commission (FTC) and Federal Deposit Insurance Corporation, along with other federal financial institution regulatory agencies, at 16 C.F.R. § 681.1 *et seq.*, to implement §114 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act) and § 315 of the FACT Act.

The Rules apply not only to financial institutions and creditors such as banks, credit unions, auto dealers, phone companies, utility companies, but to the health care industry as well, according to Kevin D. Lyles of Jones Day, and Naomi Lefkovitz of the FTC, Division of Privacy and Identity Protection. Lyles and Lefkovitz provided a detailed explanation of the requirements of the Rule and answered questions at a Society of Corporate Compliance and Ethics web conference on October 15, 2008. Many health care providers, such as hospitals, physicians, dentists, nursing homes, and other health care professionals use consumer reports (1) before offering services for which there is a delay in payment, (2) for admission purposes, or (3) as part of background checks in the employment process. Failure to comply creates civil fines for each violation, regulatory enforcement action, negative publicity and plaintiff's lawsuits.

Red flags defined. Red flags are patterns, practices, or specific activities that indicate the possible existence of identity theft, noted Lyles and Lefkowitz. The Rules contain 26 examples of potential red flags, including, but not limited to:

- applications that appear to be forged, altered, or destroyed and reassembled;
- consumer reports that include a fraud alert, credit freeze, or address discrepancy;
- change of address notice shortly followed by a request for a new credit card;
- use of an account that has been inactive for a long time.

A pertinent or relevant red flag would be highly dependent on the facility in question, said Lyles. Health care providers should examine regular business practices within their

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Wolters Kluwer Law & Business

industries to determine behaviors indicative of identity thieves. For instance, a walk-in-clinic would have different risk factors for identifying relevant red flags than an emergency room.

"Creditors" and "covered accounts." The breadth of the Rules comes from the broad definition of creditors. "Creditor" means "any person who regularly extends, renews, or continues credit; any person who regularly arranges for the extension, renewal, or continuation of credit; or any assignee of an original creditor who participates in the decision to extend, renew, or continue credit." Consequently, many health care entities may be involved in the process of extending or maintaining credit and, therefore, must comply with the Rules, even though they do not extend credit themselves. For instance, a physician that provides a medical exam, but sends a bill at the end of the month would fall under these regulations. Hospitals that defer payment for items and services, likewise, would be considered creditors. The Rules state a creditor has a duty to protect against identity theft in connection with a "covered account" that "a financial institution or creditor offers or maintains, primarily for personal, family, or household purposes, that involves or is designed to permit multiple payments or transactions."

Compliance programs. The regulations do not specify the precise nature of an established identity theft program, allowing companies a lot of flexibility in designing a program that is appropriate to the size and complexity of the company. The Rules, however, do require programs to include "reasonable policies and procedures" to identify relevant red flags, according to Lefkovitz. The speakers noted that entities with established policies and procedures related to identity theft could adapt those policies and procedures to meet the requirements of the Rules. For instance, an established compliance program that met the requirements of the Health Insurance Portability and Accountability Act privacy and security rules would be well-suited to adapt such programs for identity theft compliance. Additionally, the Emergency Medical Treatment and Active Labor Act (EMTALA) would not be superceded by the Rules; health care entities subject to EMTALA would have to fulfill those obligations prior to verifying any suspicious activity or documentation of a patient.

Oversight of the program involves: (1) assigning specific responsibilities, (2) reviewing reports, and (3) approving material changes in the program. An oversight board, board committee, or senior management designated employee would maintain oversight of the program, including reviewing reports and approving material changes to the program. It was recommended that the reports be generated annually and address material matters such as service provider arrangements, effectiveness of the polices and procedures and significant incidents.

The health care provider also should take into consideration the Rules when entering into contractual obligations with business associates, especially when relying upon billing and collecting agencies. Lefkowitz warned that because identity thieves change methods often, incorporating changes on a regular basis would be one of the best methods of ensuring a health care entity was in compliance. A health care entity that also put forth good faith efforts in complying with the Rules would not be penalized for unanticipated situations. ■

CCH Chicago Bureau, Oct. 15, 2008

Experts suggest internal audit activities based on 2009 OIG Workplan

The HHS Office of Inspector General (OIG) Workplan for 2009 gives providers the incentive to design internal audit processes that prevent mistakes in billing and cost reporting, according to speakers at a two part audioconference hosted by the Health Care Compliance Association on October 23 and 24. The first part of the conference covered issues related to hospitals, while the second part focused on physician billing issues.

In both parts, OIG senior advisor Erin Lemire gave an overview of the process of selecting items for OIG audits or evaluation studies in the coming year and questions about the specific focus of each item or reasons for investigation were answered by George M. Reeb, OIG's Assistant Inspector General for CMS Audits, and OIG senior advisor Sue Nonemaker. In the first session, the discussion was led by Regional Compliance Director of Tenet Healthcare Corporation, Lea Fourkiller, who provided specific responses for hospitals to consider. The discussion leader for the second part of the audioconference was Marti Arvin, Privacy Officer for the University of Louisville, assisted by Theresa Bivens, CPC, CHC Deputy Compliance Officer, University

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of Louisville. Bivens described how each workplan item could be incorporated in the annual audit process of a medical center or practice group.

Hospital issues. The processes used by a hospital compliance program include written instructions and training for staff involved in billing and cost reporting, but automated edits and pre-audits should be used when possible, according to the compliance professionals. The OIG looks at both manual and automated processes used by a hospital when assessing the effectiveness of its compliance program, the OIG advisors said. The 26 workplan topics for audits or evaluations specifically related to hospitals include:

- billing related to inpatient rehabilitation facility and inpatient psychiatric facility transfers;
- the appropriate use of diagnostic x-ray and interpretation in the emergency room;
- peer review of Emergency Medical Treatment and Active Labor Act (EMTALA) complaints;
- hospital pre-billing review of coding under MS-DRGs to detect upcoding;
- serious medical errors considered "never events" under the Tax Relief and Health Care Act of 2006;
- accurate reporting of wage data to support prospective payment wage indices;
- internal review process for reported disproportionate share costs;
- communication to staff regarding treatment of bad debts; and
- procedures for identifying credit balances and refunding overpayments from Medicare and Medicaid.

Some of the OIG activities are "works in progress," such as a study on Part A capital payments. In her overview, Erin Lemire explained that the OIG mission is to protect the integrity of HHS programs and the health and welfare of the beneficiaries of those programs. The items in the OIG Workplan represent not only concerns raised by HHS, Congress, or the Office of Management and Budget, but also program vulnerabilities identified in prior work by the OIG and others.

Physician issues. Compliance officers can design specific processes to evaluate their own organizations during their annual internal review with respect to OIG Workplan items, according to Theresa Bivens. For example, based on the workplan, internal reviewers could:

- run a report by place of service (POS) and pull documentation to check accuracy for certain types of service, such as ambulatory surgical services;
- check whether fewer evaluation and management services have been provided to patients since the 1992 implementation of global billing rules, whether modifier 24 (for services not included in surgical code) is used correctly, and whether follow up by a surgeon not involved in the surgery is billed correctly;
- pull claims for colonoscopies to see whether multiple procedures have been billed correctly and comply with national and local coverage determinations;
- pull claims by codes that describe services performed by nonphysicians commonly billed as "incident to" the physician's service, looking at whether the nonphysicians are practicing within the scope of their licenses and following the standards of care.

Sue Nonemaker commented that the OIG evaluation study on "incident to" services began in 2006 and involves (1) medical review, (2) evaluation of the amount of services, (3) review of patient safety issues related to the standards of care, and (4) analysis of licensure of nonphysician staff. Similarly, an OIG evaluation of "sleep studies" will involve medical review of patient charts, which is resource intensive. In contrast, other items on the OIG Workplan, such as the study of telemedicine, is focused on detecting outright fraud in claims from physicians for long distance services that are not primarily diagnostic. Another fraud scheme that OIG has included in the workplan involves provider identification numbers (IDs) obtained by entities that then reassign to a third party. Claims data shows that physician IDs have been used without the physicians' knowledge and the IDs of deceased physicians are being used to obtain Medicare reimbursement.

Among the 14 workplan projects focused on physician services, the OIG also will be looking at utilization of imaging services, which tends to vary by geographical location, appropriate referrals for home health services, and security of patient records. In a focused audit, claims will be checked for the appropriate use of the modifier "GY," which is used for services that are excluded from Medicare by statute. Examples are eye refractions and screening lab tests.

The complete OIG Workplan for 2009 is reported in the CCH *Health Care Compliance Reporter* at ¶540,052. ■

CCH Chicago Bureau, Oct. 24, 2008

On The Front Lines

Drug Compounding Activities: Another Risk Area for Compliance, Part II

by Michael E. Clark, JD, LLM, Health Care Compliance Editorial Advisory Board Member

In Part I of this Article, the current landscape of federal regulatory oversight of compounding and flaws in the Fifth Circuit's decision in Medical Center Pharmacy resulting in an inter-circuit split and increasing the likelihood that the issue of compounding will appear before the Supreme Court was discussed.

Part II of this Article addresses the potential liabilities and compliance considerations for health care professionals engaged in dispensing, marketing, or distributing compounded medications, as well as important jurisprudence regarding drug compounding.

Physicians and Pharmacists' Correlative Responsibilities

Critically, in *Thompson v. Western States Medical Ctr.*, the Court refused to make what it characterized as being the "'questionable assumption that doctors would prescribe unnecessary medications'" and rejected the government's argument that "'people would make bad decisions if given truthful information about compounded drugs.'"[20] The government had advanced a classic straw man argument because compounded drugs, by their very nature, are not subjected to the incredibly time-consuming and expensive process (averaging 10 years and around one billion dollars) required for other new drugs. And, even though the compounding process involves creating a new substance that patients can use, the vast majority of the components used to create the new substance are Food and Drug Administration (FDA) approved.

Note further that when Congress granted the FDA expanded authority to approve new drugs under the Food, Drug and Cosmetics Act, it indicated that the agency should **not** interfere with physicians' traditional discretion to practice medicine[21] (the same position that Congress took when it enacted Medicare in 1965),[22] which language also appears in the Food and Drug Administration Modernization Act.[23] Arguably, another compliance consideration to be assessed is a pharmacist's *correlative responsibilities* when the substances being compounded include controlled substances because federal law imposes a corresponding responsibility on a pharmacist—with the prescribing practitioner—to assure that the prescription was issued for a *legitimate medical purpose in the usual course of that practitioner's professional practice*. Under the federal Controlled Substance Act, any prescription issued outside these parameters is not considered to be lawful.[24]

Other Potential Liability and Compliance Considerations

Hospitals, pharmacies, and their staffs also should consider and address other potential areas of liability that may be raised by compounding medications to be administered to their patients. For example, *strict product liability* actions have been filed against hospitals and others seeking damages for injuries alleged to have been caused by the administration of unsafe compounded drugs. *Professional disciplinary actions* also have been filed by state licensure agencies against parties involved with drug compounding alleging that their conduct failed to meet the proper standards of conduct. Moreover, *insurers have resisted their obligations to cover pharmacies under professional insurance policies* alleging that drug compounding activities were not covered. As the following cases illustrate, the outcomes in these cases are notably mixed.

For example, in *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*,[25] the supreme court of Utah ruled that Stewart's Plaza Pharmacy's compounding of prescribed medications did not make it a "manufacturer" of the compounded drug that was strictly liable for damages arising from injuries to patients who used Fen-Phen, the prescribed diet combination drug. As the opinion explains, in filling five prescriptions that the plaintiff's physician issued during a nine month period, Stewart's Plaza Pharmacy compounded phentermine with fenfluramine into one-a-day Fen-Phen capsules.[26]

The plaintiff sued several parties, including the pharmacy, after she had open heart surgery to repair two damaged heart valves. The pharmacist had compounded raw fenfluramine with phentermine powder (and with methylcellulose as a time-release agent and lactose as a filler) into a one-a-day capsule, then distributed samples to local physicians for experimental use—which, in turn, generated business. Notably, the pharmacist did not test the compounded substance for safety and efficacy.

In settling her claims, Schaerrer (the plaintiff) agreed to waive recovery from any defendant who could succeed in claiming indemnity from Professional Compounding Centers of America, Inc., the manufacturer of the raw fenfluramine.[27] On appeal from the dismissal of her claims against the pharmacy, Schaerrer contended that it really acted as a manufacturer by compounding the substance and marketing it to physicians and, therefore, forfeited its right to indemnification.[28]

In analyzing this argument, the appellate court first considered the learned intermediary rule, observing that "the distribution system for prescription drugs is highly restricted," that "[p]harmacists, as suppliers, do not freely choose which 'products' they will make available to consumers in any given instance, and patients, as consumers, do not freely choose which "'product' to buy," and that "[p]hysicians exercising sound medical judgment act as intermediaries in the chain of distribution, preempting... the exercise of discretion by the supplier-pharmacist, and, within limits, by the patient-consumer."[29]

The court reasoned that the unique sets of relationships involved required it to adopt a rule that exempted pharmacists from strict product liability for not warning consumers about the risks of prescription drugs. The court explained that their ability to distribute prescription drugs is highly regulated by the FDA and that pharmacists cannot dispense such drugs without an intervening physician's prescription.[30] Moreover, the conduct of the pharmacist in compounding the drugs fell within the state's guidelines for acceptable conduct because, in creating the time-release Phen-Fen product, he had consulted with physicians about problems experienced with patients (who were not complying with instructions about properly taking the prescribed drugs), and that led him to design the new compounded medication that was not otherwise readily available.[31]

Turning to the issue of the pharmacy's marketing activities, the appeals court felt guided by *Thompson v. Western States Medical Center*,[32] which held that Congress could not prohibit pharmacists from "soliciting prescription orders or advertising or promoting the compounding of any particular drug, class of drug, or type of drug."[33] Finally, the court said, even if it assumed that the alleged activities placed the pharmacy's conduct outside acceptable guidelines, the plaintiff could not establish causation under the facts.[34]

A far different outcome was reported in *Sheffield v. State, Educ. Dept.*,[35] which upheld the authority of the New York's Commissioner of Education to sanction a hospital, its head pharmacist, and two nurses for compounding medications administered to the hospital's patients. As the court explained,

> Genesee Hospital and...the hospital's head pharmacist were found guilty of misconduct...[for] permit[ing] persons without pharmacy licenses...to dispense and mix drugs and ingredients...in preparation of hyperalimentation, peripheral intravenous solutions and intravenous solutions, an activity reserved to a trained pharmacist. The hospital was censured and reprimanded and fined $1,000 under each specification. [Its head pharmacist] was censured and reprimanded and fined $250 under each specification. Petitioners..., nurses who worked for the hospital, were charged with...unprofessional conduct...by practicing nursing beyond its scope in that they measured, weighed, compounded and mixed ingredients in preparation of intravenous solutions and prescriptions. They were censured and reprimanded and placed on probation for 18 months to insure their completion of a course of instruction in the legal aspects of nursing.[36]

Despite the nurses' equitable arguments that their conduct was the same as that which had gone on for 25 years at the hospital, and that a regulation (enacted after the proceeding) now specifically permitted such conduct, the appeals court upheld the sanctions in a terse opinion remarking that the literal wording of the applicable regulations prohibited it.[37]

A similar outcome was reported in *Gentere, Inc. v. Ohio State Bd. of Pharmacy*,[38] which involved whether a pharmaceutical company (Teregen Labs) that operated under a "wholesale distributor license" issued by Ohio's State Board of Pharmacy had violated its authority by distributing compounded drugs.

As the judge noted, when counsel for the company sought an opinion from the FDA about whether individual patient prescriptions would be required for sterile injectables to be used as part of practitioners' office stock, the FDA responded that compounding companies need to comply with Ohio's laws.[39] Subsequently, the attorney informed an officer of Teregen Labs that compounding *may* be permissible under Ohio law, citing R.C. 3715.01(A)(14)(b)(ii) (which provides that compounding performed for a physician who administers the drugs in the office is not manufacturing).

Based on this information, Teregen Labs began "a high-scale production of various injectable drugs, shipping thousands of doses to medical offices in 45 states." Within a few years, the Board conducted a routine inspection of Teregen and informed it that the Board believed the company was violating several statutes, and sent out notices for a hearing. At the conclusion of the hearing, the Board found that Teregen had violated R.C. 3715.01 and another state statute, and imposed sanctions on it and its pharmacist including a fine, cease and desist order, and revoked the pharmacist's license for six months—which led to an appeal of that decision to the trial court, which affirmed the Board's order.[40] In explaining why it rejected Teregen Labs' equitable arguments, the appellate court pointed out that the violations in question were not marginal, but flagrant:

> The problem with appellants' argument is that their practices were not consistent with "compounding" as it was defined in R.C. 4729.01(C). The evidence demonstrated appellants were producing thousands of multidose vials per month, and these vials were being shipped to medical offices around the country. Moreover, except for a single, isolated instance, none

of the orders were provided pursuant to a patient-specific prescription.[41]

In *Pharmacists Mut. Ins. Co. v. Urgent Care Pharmacy, Inc.*,[42] an insurer filed a declaratory judgment action to determine its potential liability under a professional liability policy issued to a pharmacist for damages tied to deaths and injuries resulting from the use of a contaminated drug the pharmacy had compounded. The court found for the defendant pharmacy on summary judgment. As the court explained, the pharmacy had been asked by a pain treatment physician to compound the medication (methylprednisolone) after its manufacturer (UpJohn) stopped commercially manufacturing it.[43] In an attempt to avoid its obligations under the insurance policy, the insurer claimed that the pharmacy's conduct was commercial in nature, because it had compounded the substances in advance (meaning that such activities were not "individualized" for patients as is characteristic of traditional compounding activities) and had advertised and marketed its services. In addressing these arguments, the court explained that because the subject matter involved construing the terms of an insurance policy, it was guided by case precedent that required it to construe such language liberally in favor of the insured (and strictly against the insurer) if the policy's terms were ambiguous.[44]

In going through each of the arguments, the court found that either the policy covered the conduct or that the policy's terms were ambiguous, and, therefore, construed them in favor of the insured.

Hoffman-La Roche Inc. v. Medisca, Inc.[45] involved a different theory of liability for entities in the distribution chain of compounded pharmaceuticals. In his decision, the trial judge explained why he had ruled against granting injunctive relief in this action filed under state statutes and under the federal Lanham Act[46] for the manufacturer of a successful injectable antibiotic against the importer and distributor of bulk pharmaceuticals whose customers used these generic chemicals to compound pharmaceuticals. In analyzing the pharmaceutical manufacturer's first theory, the judge found that while Hoffman-La Roche could prove that its product met the standards for trademark protection, it was not likely to prevail on the merits because the manner in which Medisca advertised its product was unlikely to confuse consumers.[47] Hoffman-La Roche made a related claim that confusion as to the source of the drug was likely because Medisca's sale of the product under its generic name was in violation of the Food, Drug, and Cosmetic Act and its implementing regulations. In rejecting this argument, and touching upon the FDA's authority over compounding activities, the judge wrote:

> The position Roche urges would also require the Court to accept that the consumer knows that a seller, like Medisca, has not obtained FDA approval to sell ceftriaxone sodium. *Similarly, it would require the consumer to understand that a seller, like Medisca, does not fit within the compounding exception under the FFDCA, and is thus required to obtain FDA approval before selling the chemical.*
> (Emphasis supplied).[48]

Conclusion

Successful compliance efforts require proactive steps that are tailored to prevent or at least minimize conduct that places individuals and institutions at risk. Although the extent and quality of compliance efforts in the past few decades have vastly improved in light of various administrative, civil, and criminal actions, risk areas such as those posed by drug compounding activities may be significant, but not as well understood, because they have not achieved the degree of prominence and notoriety. As this article illustrates, state and federal laws that address the limits of permissible and unlawful drug compounding activities are not as well understood and remain in flux. If hospitals, pharmacies, and their staffs violate these provisions, they can be exposed to administrative, civil, and even (in rare instances not covered in this discussion) criminal actions. It appears that this risk area is one that will continue to get increasing attention by regulators and private litigants, so the scope and extent of drug compounding activities need to be assessed by compliance officers when designing and updating compliance plans. ■

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[20] Conant v. Walters, 309 F.3d 629, 637 (9th Cir. 2002) (citing Thompson v. Western States Medical Ctr., 535 U.S. at 357).

[21] As the FDA previously has noted, the "FDCA's legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine" and that the "FDCA does not regulate physicians in their practice because physicians are licensed by the states." *See* Chaney v. Heckler, 718 F.2d 1174, 1179-80 (D.C. Cir. 1984) (death penalty challenge to states' use of lethal injection drugs not being FDA-approved and proven "safe and effective" for human execution) (internal note omitted, observing that "the legislative history makes clear that Congress did not want to limit a physician's ability to treat his patients."), rev'd on other grounds, Heckler v. Chaney, 470 U.S. 821 (1985).

[22] The very first section of the Act, codified at 42 U.S.C. § 1395(Prohibition against any Federal interference), makes this point quite clear:

> Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the *practice of medicine or the manner in which medical services are provided*, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

(Emphasis added) (Aug. 14, 1935, ch. 531, title XVIII, Sec. 1801, as added Pub. L. 89-97, title I, Sec. 102(a), July 30, 1965, 79 Stat. 291.).

[23] Section 214 of the FDAMA, codified at 21 U.S.C. § 396 (Practice of Medicine) provides: "Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." *See also*, generally, Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149 (2004).

[24] *See* 21 C.F.R. § 1306.04 (Purpose of issue of prescription), which provides, in relevant part, that:

> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.* An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(Emphasis supplied).

[25] Schaerrer v. Stewart's Plaza Pharmacy, Inc., 79 P.3d 922 (Utah 2003).

[26] *Id.* at 925.

[27] *Id.* at 925-926.

[28] *Id.* at 926.

[29] *Id.* at 929.

[30] *Id.*

[31] *Id.* at 930.

[32] Thompson v. Western States Medical Center, 535 U.S. 357, 365, 377 (2002).

[33] *Id.*

[34] *Id.* at 933.

[35] Sheffield v. State, Educ. Dept., 174 A.D.2d 855 (N.Y.A.D. 3 Dept. 1991).

[36] *Id.* at 350-51.

[37] *Id.* at 351-52.

[38] Gentere, Inc. v. Ohio State Bd. of Pharmacy, 2006 WL 2535726 (Ohio App. 11 Dist.) (Slip Op.).

[39] *Id.* at *2.

[40] *Id.*

[41] *Id.* at *5.

[42] Pharmacists Mut. Ins. Co. v. Urgent Care Pharmacy, Inc., 413 F.Supp.2d 633 (D.S.C. 2006).

[43] *Id.* at 635.

[44] *Id.* at 637.

[45] Hoffman-La Roche Inc. v. Medisca, Inc., 1999 WL 123578 (N.D.N.Y.).

[46] As the judge explained,

> Section 43(a) of the Lanham Act provides a private cause of action against any person who "in connection with any goods...uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, which is likely to cause confusion...as to the affiliation, connection, or association of such person with another, or as to the origin, sponsorship, or approval of his or her goods...by another person." 15 U.S.C. § 1125(a)(1)(A).

Id. at *2.

[47] *See Id.* at *4.

[48] *See Id.* at *5.

Tax-exempt Organizations

IRS official: New Form 990 "a work in progress"

The redesigned Form 990 annual tax return filed by tax-exempt organizations is "a work in process, " said Ronald Schultz, senior technical advisor to the Internal Revenue Service (IRS) Commissioner (Tax Exempt and Government Entities), during an October 15 program sponsored by the Washington D.C. Bar Association.

For example, Schultz noted, the IRS has not solved how to require consolidated reporting or determined whether to include certain hospital expenditures as a community benefit. The IRS previously announced that it is considering requiring organizations to identify the sector for its program service activities. It also may require reporting of payments to family members who are government officials.

Ongoing revisions. The goal of the form is "complete and accurate reporting" of an organization's operations, Schultz explained. If reporting on the new form does not appear to be complete or adequate, and organizations are struggling to answer certain questions, the IRS will consider revisions.

Other Form 990-related projects that the IRS is working on include:

- burden reduction;
- timely public access to the form;
- examples of program service accomplishments;
- programs to improve the completeness and accuracy of the form;
- activity codes to be reported in relation to program services; and
- reasonable efforts or similar criteria that will apply to expenses for government officials.

Compliance and transparency. Questioned about the broad scope of questions on the redesigned form, Schultz replied that he believes the IRS has jurisdiction "to ask every question on the new form," including governance. The form's primary purpose is compliance, although transparency is another goal. For example, the nonprofit sector asked for a question on the number of volunteers so that organizations operating primarily through volunteers could give a truer picture of their operations.

Schultz agreed with program moderator Roger Colinvaux of Catholic University Law School that reporting compliance is a concern and that the IRS, over time, will need to revisit the penalties for not filing or for incomplete filing. Schultz did not know whether reporting noncompliance reflects lack of IRS enforcement, weak penalties, or problems with the form.

Colinvaux and Schultz agreed that the nonprofit sector expects more enforcement action from the IRS based on the additional information provided by the new form. ■

CCH Washington Bureau, Oct. 20, 2008

Anit-Kickback

OIG permits prescription drug proposal

The Office of Inspector General (OIG) would not impose sanctions related to a proposed arrangement that would allow a charitable organization to provide financial assistance to cover cost-sharing obligations associated with outpatient drug treatment for financially needy Medicare or Medicaid patients and was reliant upon donor funds, because it was designed with sufficient safeguards.

The patient assistance program would focus primarily on increasing access to high-cost, medically necessary drug treatment options that were often skipped by patients who could not afford to pay. All prospective assistance recipients would be required to complete an application on a first-come, first-served basis, to the extent funding was available. Grants would be awarded pursuant to assessment of the applicants' individual financial needs based on national standards of indigence. The organization would provide financial assistance for so long as the participating patient continued to meet the program's eligibility criteria. The patient assistance program would be governed by an independent board of directors, which would handle all policy-making functions, such as the determination of patient eligibility requirements.

The proposed design and administration of the patient assistance program interposed an independent charitable organization between donors and patients in a manner that effectively insulated beneficiary decision-making from information attributing the funding of the benefit to any donor. It was unlikely that donor contributions would influence any patient's selection of a particular provider, supplier, product, or insurance plan. The patient assistance program also did not take into account (1) the identity of provider, practitioner, supplier of items or services, or drug or other product the applicant may use; (2) the identity of referring person or organization; or (3) the amount of contributions made by a donor whose services or products were used or may be used by the applicant. ■

OIG Advisory Opinion, No. 08-37, Oct. 21, 2008
Health Care Compliance Reporter, ¶500,197

In the News

Physician's progress notes are material

A physician's progress notes may constitute material misrepresentations and materially false, fictitious, or fraudulent statements or representations under 18 U.S.C. §§1347 and 1035 because the notes were used to make a Medicare claim, although the notes were not submitted to Medicare, according to a Pennsylvania district court. A physician had his employees generate progress notes that falsely represented that certain services were provided to support claims submitted to Medicare. The statute does not require that the alleged falsehoods be submitted to Medicare or otherwise relied upon to be punishable. It is considered health care fraud to make materially false statements, representations, or use a materially false document or writing containing a materially false statement or entry in connection with the delivery of or payment for health care benefits or services. When Medicare audits a provider's billings, it does so by comparing the physician's entries in his or her progress notes to the claimed procedure.

U.S. v. Salko, Oct. 20, 2008, Health Care Compliance Reporter, ¶800,577

OIG: HIPAA compliance needs more oversight

CMS should be more proactive in its efforts to ensure that health care providers are complying with the Health Insurance Portability and Accountability Act (HIPAA), according to an Office of Inspector General (OIG) report. The OIG recommended that CMS establish policies and procedures for conducting regular HIPAA Security Rule compliance reviews. CMS is responsible for interpreting, implementing and enforcing HIPAA Security Rule provisions and also has the authority to impose civil monetary penalties for violations of the rule. CMS has not conducted any compliance reviews of covered entities since 2003 when HHS assigned the role. Rather, the agency has relied on complaints to identify incidents of noncompliance to investigate. CMS has no effective mechanism to ensure that covered entities are complying with the HIPAA Security Rule or that electronic protected health information is being protected, the OIG report noted . After the OIG conducted its fieldwork, but before its report was issued, CMS executed a contract to conduct compliance reviews.

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Outpatient quality of care changes

CMS announced plans to strengthen the tie between the quality of care furnished to people with Medicare in hospital outpatient departments (HOPDs) and the payments hospitals receive for those services. In a final rule establishing Medicare payment and policy changes for services in HOPDs and ambulatory surgical centers (ASCs) for calendar year (CY) 2009, the implementation of Value Based Purchasing (VBP) initiatives across the continuum of beneficiaries' care would continue to transform Medicare from a passive payer to a prudent purchaser of health care. The changes in the final rule will apply to outpatient services furnished by more than 4,000 HOPDs in general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term care hospitals, community mental health centers, children's hospitals, and cancer hospitals. The final rule emphasizes CMS' existing administrative authority to develop and implement a policy that would not pay hospitals for care related to illness or injuries acquired by the patient during a hospital outpatient encounter. Such a policy would make adjustments to OPPS payments to ensure equitable and appropriate payment for care, similar to the quality adjustments applied to payment for hospital-acquired conditions in the inpatient setting. The final rule will appear in the November 18, 2008, *Federal Register*. ■

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