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The shortage of primary care providers and healthcare reform – what compliance officers should be prepared for

by Paul R. DeMuro, JD, CPA, MBA, CHC, FHFMA, FACMPE

Any form of health care reform likely will result in more individuals having some form of insurance coverage. As many as 46 to 47 million uninsured individuals may have insurance coverage under health care reform. With many areas of the country already without sufficient primary care provider capacity, how will the system react? Will the lines at Emergency Departments at hospitals be longer like in Massachusetts after it enacted its own form of health care reform? Will more primary care physicians, like those in San Francisco, seek to be concierge providers further exacerbating the shortage?

A likely unintended consequence of health care reform is greater difficulty in accessing primary care services. The concept of every individual in the U.S. having a medical home is laudatory, but just how will this happen when there already is a shortage of primary care capacity? Early retirement by physicians and lack of sufficient nursing school teachers does not help the situation.

Compliance officers should be prepared to address many of the following unintended consequences that health care reform likely will bring as a result of a probable increasing primary care shortage.

- Physician recruitment efforts will be much more difficult, particularly in the primary care area. Compliance officers will need to pay particular attention to these relationships and contracts to ensure that they are consistent with applicable law and regulations, as there will be an incentive to "push the envelope" to get the recruit. It will be important to make sure fair market value compensation analyses will keep pace.
- Contracts for emergency department physicians and allied health professionals staffing and/or employment contracts in this area will have to keep pace with the increasing patient loads in emergency departments. Compensation and/or subsidies to physicians likely will have to rise. A greater use of physician extenders will have to be made. Emergency department redesign may be necessary, but where will all the new professionals come from? Compliance officers will have to keep abreast of these newly evolving relationships and

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whether they are consistent with applicable law and regulations.

- Relationships between medical schools/medical residents and hospitals and physician groups hoping to employ newly minted physicians likely are to become strained. As competition for such physicians increase, compliance officers should closely monitor these situations.
- Accountable Care Organizations (ACO)/Next Generation Integrated Delivery Systems (IDS) will develop and flourish along with emerging clinical integration models, greater use of electronic health records, telemedicine, robotics and medical informatics in an attempt to align incentives, and reduce costs in the context of improving quality. A myriad of new relationships will develop as a result of each of these aspects of ACO/IDS development. Compliance officers will have to recognize the gainsharing, pay for performance (P4P), and incentive payment mechanisms, and be prepared to ensure that they are consistent with applicable law and regulation. Electronic health records, how they are employed, telemedicine, robotics, and the implementation of medical informatics to a greater extent in the delivery of care will raise many HIPAA, privacy, quality of care, practice of medicine, and accreditation concerns in addition to the traditional Medicare and Medicaid fraud and abuse and Stark self-referral rules.
- Relationships with nursing schools will become even more key, particularly as health systems strive to bring on physician extenders and team approaches to primary care. Joint venture and support relationships with nursing schools will become more common. Compliance officers will need to be prepared to scrutinize these relationships and ensure they are compliant.
- Hospital on-call relationships with physicians will be strained. Add 46 to 47 million new prospective patients accessing emergency departments. Many will have the need for medical care beyond what is available in the emergency department and the physicians from the call schedule will be called to the hospital. With just about everyone having healthcare insurance coverage, will the payments made for such patients be sufficient to the physicians called in, or will they seek additional monies from the hospitals? Will there be enough physicians on-call in each specialty? Compliance officers will have to closely monitor these situations and any new contracts/arrangements/payments and their legal and regulatory implications.
- Medical groups may be in even greater need of primary care capabilities. Will they seek some form of assistance from their local hospitals to ensure that the medical groups do not implode? If so, how will hospitals respond? And will these responses be consistent with applicable law and regulations? Compliance officers will need to know.
- Community clinics may be a factor in helping to establish medical homes for individuals without them. Will hospitals seek to support such efforts? Many do today. Compliance officers need to be aware of such relationships and how they might affect their efforts.
- Advances in science and technology directed at improving the management of the health of patient populations, including disease state management, episodic care advances, the use of advanced pharmaceutical therapies and medical devices can all result in increasingly difficult compliance issues which compliance officers will need to address. Compliance officers must understand these developments and be prepared for their consequences.
- Last but not least, the dynamics of the market and continuing changing nature of all aspects of the health care industry system to accommodate healthcare reform, payment mechanisms, relationships with insurers, managed care companies, and the public option or healthcare cooperatives need to be followed closely. Compliance officers need to be prepared to address whatever may come at them. Thus, they need to be prepared for the unexpected. ■

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Fraud and Abuse

New requirements effective for suppliers of medical equipment and supplies

Most suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) were required to have met new quality standards by October 1, 2009, and obtain a surety bond by October 2, 2009, as required by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and the Balanced Budget Act of 1997 (BBA).

In order to obtain Medicare billing privileges, DMEPOS suppliers must become accredited by meeting Medicare's business and product-specific service and quality standards. The business standards include: (1) how the company is run, (2) how finances and staff performance are managed, (3) how well the company takes care of its consumers, (4) the safety of their products, and (5) whether the company's information management systems are in place. The product-specific service standards include: (1) intake, (2) delivery and setup, (3) training and instruction of the beneficiary and their caregiver, and (4) follow-up service.

According to CMS, the vast majority of Medicare DMEPOS suppliers have met the deadlines to apply and become accredited. CMS is continuing to work to complete the evaluations of those suppliers whose accreditation applications are still under review, which could take as long as 60 days. Suppliers wishing to participate in the Medicare DMEPOS competitive bidding program must be fully accredited to submit a bid.

CMS-deemed accreditation organizations have been required by the MMA to use these new quality standards to evaluate the applications of thousands of DMEPOS suppliers during the past three years. More than 50,000 DMEPOS suppliers (70 percent) have already been accredited.

The accreditation requirement applies to suppliers of durable medical equipment, medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral/enteral nutrition, transfusion medicine and prosthetic devices, prosthetics and orthotics unless a professional exemption applies. Pharmacies, pedorthists, mastectomy fitters, orthopedic fitters/technicians and athletic trainers must also comply.

Congress is considering extending the deadline for pharmacies to meet this accreditation requirement to January 1, 2010, with the exception of those pharmacies that plan to bid in the DMEPOS competitive bidding program.

The BBA surety bond requirement requires certain DMEPOS suppliers to obtain and maintain a $50,000 surety bond. The surety bond limits the risk to the Medicare program from fraudulent equipment suppliers and helps to ensure that Medicare beneficiaries receive medical items that are "reasonable and necessary" from legitimate suppliers. ■

CMS Fact Sheet, Oct. 1, 2009

HIPAA

Proposed, final rules protect patients' genetic information

Individuals' genetic information will have greater protections through an interim final rule recently issued by CMS, the Employee Benefits Security Administration, the Internal Revenue Service and proposed regulations issued by the Office of Civil Rights (OCR) implementing the Genetic Information Nondiscrimination Act of 2008 (GINA) (PubLNo 110-233).

GINA provisions. GINA protects individuals against discrimination based on their genetic information in health coverage (Title I) and employment (Title II). GINA established three rules that generally prohibit a group health plan and a health insurance issuer in the group market from: (1) increasing the group premium or contribution amounts based on genetic information; (2) requesting or requiring an individual or family member to undergo a genetic test; and (3) requesting, requiring, or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

Interim final rule. Under the interim final rule, group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare supplemental policies cannot: increase premiums for the group based

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On The Front Lines

The Role of Data Monitoring Committees (DMCs) in Clinical Trials

by Patricia Brent, JD, MPH

The organization and management of a clinical research program has many functional and complex parts and their roles are ever-expanding. Data Monitoring Committees (DMCs) have been a component of some clinical trials since at least the early 1960s but, until recently, they were used primarily in large multi-centered trials sponsored by federal agencies, such as the National Institutes for Health (NIH), the National Cancer Institute (NCI) and the Department of Veterans' Affairs (VA). Few clinical trials sponsored by pharmaceutical or medical device manufacturers incorporated DMC oversight into their protocols. This article describes the role and functions of a DMC and details DMC requirements for three different government research-funding agencies.

Today, the increasing importance of including DMCs in clinical trials is the result of several factors: (1) the growing number of industry-sponsored trials with mortality or major morbidity endpoints; (2) increasing collaboration between industry and government in sponsoring major clinical trials, resulting in industry trials performed under the policies of the government funding agencies, which often require DMCs; (3) heightened awareness within the scientific community of problems in clinical trial conduct and analysis that might lead to inaccurate and/or biased results, especially when early termination for efficacy is a possibility, and need for approaches to protect against such problems; and (4) concerns of institutional review boards (IRBs) regarding on-going trial monitoring and patient safety in multi-centered trials.

A DMC is an independent committee of scientists, physicians, statisticians and community representatives that collect and analyze the clinical data generated during the course of a clinical trial to monitor for adverse effects and other clinical trends, such as an indication that one treatment is significantly better than another, especially when one "arm" of the trial involves a placebo control that might: (1) warrant modification of the protocol or termination of the trial, (2) warrant notification of the trial participants about any new information that might affect their willingness to continue participating in the trial, or (3) have an adverse effect on their morbidity or mortality.

It is important to understand, however, that the data and safety monitoring function and oversight of these activities conducted by a DMC are distinct from the requirements for clinical trial protocol review and approval by a research institution's IRB, whose functions are more commonly known within the research world.

Current Practice

The National Cancer Institute (NCI), the Food and Drug Administration (FDA) and the International Conference on Harmonization (ICH) all have issued guidelines for the establishment, formation and best practices of a DMC, including criteria for deciding which trials need a formal DMC.[1]

The initial recommendation for establishing a DMC was based on the recognition that interim monitoring of accumulating study data was essential to ensure the on-going safety of trial participants, but acknowledged that individuals closely involved with the design and conduct of a clinical trial might not be able to be fully objective in reviewing a trial's interim data for any emerging concerns. Thus, involvement of expert advisors who were external to the clinical trial organizers, sponsors and/or investigators, through the use of a DMC, was recommended as an approach to help ensure that identified problems in clinical trials would be addressed in an unbiased manner.

DMCs are presently employed in a variety of situations, and several different operative models are used. Although no single model may be optimal for all settings, and there is not necessarily consensus about the optimal model in any given setting, there are advantages and disadvantages with respect to some of the different approaches that are used. As mentioned above, government agencies that sponsor clinical research, such as the NIH, the NCI and the VA, now require DMCs for certain types of clinical trials. Current FDA regulations, however, impose no requirements for DMCs in clinical trials, except under 21 C.F.R. § 50.24(a)(7)(iv) for research studies that are conducted in emergency settings, where the informed consent requirement is excepted.

The Role of Oversight Groups

Several groups and individuals share responsibility for various aspects of clinical trial monitoring and oversight functions. The sponsor of a clinical trial takes responsibility for and initiates the investigation.[2] The sponsor may be an individual, a company, university, hospital or government agency, or some

combination, that holds the investigational new drug application (IND) or investigational device exemption (IDE) and/or has responsibility for designing, initiating, funding, managing, coordinating, continuing, and/or concluding a clinical trial.

Typically, the sponsor holds the IND or IDE.[3] When the IND or IDE holder is also a study investigator, that individual is considered to be a sponsor-investigator.[4] It is important that the responsibilities and authorities of the product manufacturer, the funding organization (if different) and any other entity be clearly defined and understood by all parties at the trial's start. Potential conflicts of interest of each party, especially the sponsors and the clinical investigators, should be carefully considered when determining the roles and responsibilities.[5]

Study investigators have the primary responsibility for identifying potential adverse effects experienced by study participants, adjusting the intervention accordingly and reporting the experience to the sponsor. The sponsor is responsible for monitoring and analyzing these investigator reports and relaying them, as outlined in the regulations, to the FDA, other regulatory authorities and other investigators.[6] The sponsor and the FDA, respectively, also review adverse experience reports from all trials of a given product. For medical device studies, sponsors are responsible for assuring that the FDA and any reviewing IRB are promptly informed of significant new information about the course of the trial. For drugs and biologics studies, sponsors must notify IRBs, as well as the FDA and other investigators, if the sponsor withdraws the IND for a safety-related reason.

IRBs, on the other hand, are responsible for evaluating a clinical trial to determine, among other things, whether the "risks to subjects are minimized" and those risks are reasonable in relation to anticipated benefits.[7] An IRB evaluation entails review of the study protocol, relevant background information, the informed consent documents, proposed plans for informing participants about the trial and any other procedures associated with the trial. To determine whether risks to subjects are minimized by "using procedures which are consistent with sound research design," an IRB may request information from the sponsor about the approach to trial monitoring, including the statistical basis for early termination, and what steps the sponsor is taking to minimize the risks to patients.[8] As part of its oversight responsibility, an IRB may inquire whether a DMC has been established and, if so, seek information about its scope and composition.

For example, in ongoing clinical trials, the IRB is responsible for considering information arising from the trial that may bear on the continued acceptability of the trial at the clinical study site it oversees.[9] A DMC, on the other hand, generally has access to much more data than the IRB during the trial itself, including interim efficacy and safety outcome by treatment arm, and can make recommendations with regard to the entire trial, not just the trial being conducted at a particular site.

In addition to the IRB, a clinical trial may have other committees involved in monitoring and evaluating its efficacy and safety, such as a clinical trial steering committee, endpoint assessment/adjudication committee, and/or a site monitoring committee(s). Each has its specific role and must interact appropriately with the IRB and DMC.

DMC Committee Composition

Although each Data Safety Monitoring policy (e.g., NIH, NCI, FDA) outlines its particular guidelines for a DMC, there are important similarities among them. One example is the composition of the committee. Factors for selecting individuals to serve on a DMC include relevant experience, experience in clinical trials and in serving on other DMCs, the absence of serious conflicts of interest with the objectives and design of the clinical trial, with the scope of responsibilities given to the DMC determining the types of expertise that are needed for a particular DMC.

Most DMCs are composed of clinicians with expertise in relevant clinical specialties and at least one biostatistician knowledgeable about statistical methods for clinical trials and sequential analysis of trial data. For trials with unusually high risks or with broad public health implications, the DMC may include a medical ethicist knowledgeable about the design, conduct and interpretation of clinical trials. Some trials may require a DMC member with special expertise, such as a toxicologist, an epidemiologist, or a clinical pharmacologist. In certain circumstances, one or more non-scientists who bring the perspective of the population under study may be useful, such as someone with the disease or condition under study or a close relative of such an individual. In some trials, appropriate representation of gender or ethnic groups also may be important. DMCs in clinical trials that are conducted internationally usually include representatives from a subset of the participating countries or regions. Finally, one of the most important criteria for selecting a committee member is the member's ability to commit to attending the meetings and carrying out their responsibility as a committee member.

The possible existence of conflicts of interest in potential committee members deserves special consideration. The most obvious conflict is a financial interest in the product under study. There can also be "intellectual" conflicts of interest, as in when a committee member has particularly strong views on the relative merit of the intervention being studied.

The DMC Charter

DMCs operate under a written charter that includes well-defined standard operating procedures. Such charters are important for the same reason that study protocols and analytical plans are important—they document that procedures were pre-specified and thereby reduce concerns that trial operations inappropriately may have influenced the interim data, thus biasing trial results and interpretation. Charter topics include meeting schedule and format, format for data presentation, specification of who has

access to the interim data, who may attend all or part of DMC meetings, procedures for assessing conflicts of interest of potential DMC members, the method and timing of providing interim reports, and other issues relevant to committee operations.

DMC Meetings

The Charter also describes the format and frequency of DMC meetings. Included in this are a description of the permitted attendees, the types of meetings to be held, their format, frequency and the expected outcome of the meeting. While face-to-face meetings are the norm, there may be times when telephone conferences are appropriate, especially when new information must be considered.

Many DMC meetings include an "open" session in which information in the open report is discussed. This information may include the status of recruitment, baseline characteristics, ineligibility rate, accuracy and timeliness of data submissions, and other administrative data provided to the committee.

"Open" sessions may include sponsor representatives, steering committee members, study investigators, FDA representatives (or NCI program staff) or others with clinical trial responsibilities. The study interim data, however, is almost exclusively considered within the "closed" session part of the meeting, which is attended only by the DMC members and the statistician who prepared and is presenting the interim analyses.

Other Important Issues

Additional important issues to be addressed by the Charter include DMC reporting requirements and record keeping procedures requirements. The DMC usually generates a significant amount of records, including the minutes of both open and closed meetings, and the summary of the interim data analyses. The maintenance of these records, such as data back-up requirements and document destruction policies, are also important issues to be addressed.

NIH Policy for DMCs

Each institute and center within the NIH must have a system for appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data for all NIH-supported or conducted clinical trials.[10] Establishment of a DMC is required for all multi-site clinical trials involving interventions that entail potential risk to the participant in order to determine the safety and effectiveness of the trial and to recommend its conclusion when significant benefits or risks have developed or when the trial is unlikely to be concluded successfully.

The current NIH policy includes monitoring for all types of clinical trials, including physiological, toxicity, and dose-related studies (Phase I), efficacy studies (Phase II), and efficacy, effectiveness and comparative trials (Phase III). The method and degree of monitoring required are related to the degree of risk involved and are designed to be commensurate with the size and complexity of the trial. For Phase I and Phase II trials, a DMC may be appropriate when the studies have multiple clinical sites, are blinded, or employ particularly high risk interventions or vulnerable populations, such as children, the elderly or pregnant women, or populations of terminally ill patients or those with diminished mental capacity.[11]

The NIH policy outlines the minimum responsibilities that its institutes and/or centers must assume, including:

- prepare or ensure the establishment of a plan for data and safety monitoring for all interventional trials;
- conduct or delegate ongoing monitoring of interventional trials;
- ensure that monitoring is timely and effective and that those responsible for monitoring have the appropriate expertise to accomplish its mission;
- oversee monitoring activities; and
- respond to recommendations that emanate from monitoring activities.

In addition, the expectations on how monitoring must be performed, the plans for reviewing the research protocol, the plans for data and safety monitoring and the formation and conduct of the committee and its meetings are outlined.

In June 2000, the NIH published further DMC guidance for Phase I and Phase II clinical trials.[12] It requires investigators to submit a general description of the data and safety monitoring plan as part of their research application. This plan is then reviewed by the NIH scientist review group and any comments/concerns noted are included in an administrative note in the grant summary statement. A detailed monitoring plan must then be included as part of the study protocol, which is submitted to the local IRB for review and approval.

At a minimum, all plans must include a description of the reporting mechanisms of adverse events to the IRB, the FDA, and the NIH. Investigators must ensure that the NIH be informed of actions taken by an IRB as a result of any continuing review process. The Guidance also includes specific reporting requirements, necessary elements of the monitoring plan, and requirements for multi-site Phase I and Phase II trials.

NCI Policy on Data Monitoring

All clinical trials supported or performed by NCI require some form of monitoring.[13] Like the NIH policy, NCI's policy states that the methods and degree of monitoring should be commensurate with the degree of risk to trial participants and the size and complexity of the clinical trial. Monitoring exists on a continuum– from monitoring by the principal investigator/project manager or NCI program staff to a formal data and safety monitoring committee. NCI program staff is responsible for oversight of the monitoring activity.

Phase I and Phase II studies may be monitored by the principal investigator/project manager, by NCI program staff or a designee, or jointly. When the trial is conducted by the principal investigator/project manager, the awardee must have in place written policies and procedures describing the monitoring and reporting processes, consistent with NCI policies. NCI program staff then determines their acceptability. All Phase III randomized clinical trials supported or performed by NCI require monitoring by a DMC.

The DMC is responsible for reviewing: (1) interim analyses of outcome data and cumulative toxicity data summaries to determine whether the trial should continue as originally designed, should be changed, or should be terminated based on the data; (2) reports of related studies to determine whether the monitored

study needs to be changed or terminated; and (3) major proposed modifications to the study prior to their implementation (e.g., termination, dropping an arm based on toxicity results or other reported trial outcomes, increasing target sample size, etc.).

The FDA's Guidance for DMCs

Sponsors of clinical trials studying products regulated by the FDA (e.g., new drugs, biologics, and medical devices) are required to monitor these studies as they progress.[14] As mentioned above, however, current FDA regulations impose no requirements for the use of DMCs, except for research studies in emergency settings where informed consent is excepted. Because not all clinical trials are supported or conducted by NIH or the NCI or the VA—i.e., they are sponsored and conducted by the product manufacturer (a pharmaceutical company or a medical device manufacturer), the FDA guidelines for a DMC differ in some respects from the NIH or NCI guidelines.

Under the FDA guidance for DMCs, DMCs generally are established for large, randomized multi-site studies that evaluate treatments intended to prolong life or reduce risk of a major adverse health outcome, such as a cardiovascular event or a recurrence of cancer. DMCs are recommended for controlled trials of any size that will compare rates of mortality or major morbidity, although a DMC is not required or recommended for many clinical studies. Generally, they are not needed for trials of products that are in the early stages of development or for trials addressing lesser outcomes, such as symptomatic relief, unless the trial population is at an elevated risk for more severe outcomes.

When determining whether to establish a DMC for a particular trial, the FDA recommends several factors to be considered:

- whether the study endpoint is such that a highly favorable or unfavorable result, or even a finding of futility, at an interim analysis might ethically require termination of the study before its planned completion;
- whether there are *a priori* reasons for a particular safety concern, e.g., if the procedure for administering the treatment is particularly invasive;
- whether there is prior information suggesting the possibility of serious toxicity with the study treatment;
- whether the study is being performed in a potentially fragile population such as children, the elderly or pregnant women, or other vulnerable populations such as those who are terminally ill or of diminished mental capacity;
- whether the study is being performed in a population at elevated risk of death or other serious outcomes, even when the study objective addresses a lesser endpoint; and
- whether the study is large, of long duration or multi-centered.

Another consideration is whether a DMC review will be practical. If the trial is likely to be completed quickly, the DMC may not have an opportunity to have meaningful impact. Some short-term trials with important safety concerns, however, may still warrant a DMC.

An additional issue is whether a DMC can help assure scientific validity (and the perception of such) for a trial. Because trials of any appreciable duration can be affected by changes over time in the understanding of the disease, the population under study, and the standard treatment used outside the clinical trial regimen, these external changes may prompt an interest in modifying some aspects of the trial as it progresses.

Conclusion

DMCs have become an important and integral part of the clinical trial process. Ultimately, they protect the safety of the clinical trial participant, as well as the integrity and validity of the study. The policies and procedures for operating a DMC are important to their overall success and, thus, guidance documents from federal agencies and study sponsors must be followed to ensure compliance and effectiveness. ■

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1 National Cancer Institute Data and Safety Monitoring Guidelines, *available at* http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines; National Institutes for Health: NIH Policy for Data and Safety Monitoring, *available at* http://grants1.nih.gov/grants/guide/notice-files/not98-084.html; Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials, *available at* http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html; U.S. Food and Drug Administration, Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees, *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm127069.htm; U.S. Department of Veterans' Affairs, Cooperative Studies Program: Guidelines for Planning and Conduct of Cooperative Studies, Office of Research and Development, January, 2001; International Conference on Harmonization, Good Clinical Practice: Consolidated Guidelines; and Statistical Principles for Clinical Trials, *available at* http://www.ich.org/.

2 *See* 21 C.F.R. § 50.3(e); 21 C.F.R. § 312.3 and 21 C.F.R. § 812.3(n).

3 21 C.F.R. § 312.40(a)(1); 21 C.F.R. § 812.40.

4 21 C.F.R. § 312.3(b); 21 C.F.R. § 812.3(o).

5 21 C.F.R. Part 54.

6 21 C.F.R. § 312.32(c); 21 C.F.R. § 812.40.

7 21 C.F.R. § 56.111(a).

8 21 C.F.R. § 5.111(a)(1)(i).

9 21 C.F.R. § 56.103.

10 National Institutes' for Health, Policy for Data and Safety Monitoring, June 10, 1998, *available at* http://grants.nih.gov/grants/guide/notice-files/not98-084.html.

11 *Id.*

12 *Id.*

13 National Cancer Institute, Policy of the National Cancer Institute for Data and Safety Monitoring of Clinical Trials, June 22, 1999, NCIDEA: Data and Safety Monitoring of Clinical Trials, *available at* http://deainfo.nci.nih.gov/grantspolicies/datasafety.htm.

14 U.S. Food and Drug Administration, Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees, March 2006. *See also* 21 C.F.R. § 312.50 and 21 C.F.R. § 312.56 for drugs and biologics, 21 C.F.R. § 812.40 and 21 C.F.R. § 812.46 for devices.

on the results of one enrollee's genetic information, deny enrollment, impose pre-existing condition exclusions, or do other forms of underwriting based on genetic information. The interim regulations also prohibit group health plans and health insurance issuers in the group and individual markets from requesting, requiring, or buying genetic information for underwriting purposes or in connection with enrollment; and asking individuals or family members to undergo a genetic test.

The interim final regulations for the group market apply to group health plans and group health issuers for plan years beginning on or after December 7, 2009. The interim final regulations for the individual market apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

OCR's proposed rule. OCR's proposed rule would implement Section 105 of Title I of GINA regarding the privacy and confidentiality of genetic information and amend the HIPAA Privacy Rule to prohibit health plans from using or disclosing genetic information for underwriting purposes. The proposed rule modifies the Privacy Rule to (1) explicitly provide that genetic information is health information for purposes of the Privacy Rule, (2) prohibit health plans from using or disclosing protected health information for underwriting purposes, (3) revise the provisions related to the Notice of Privacy Practices for health plans that perform underwriting, (4) make a number of conforming modifications to definitions and other provisions of the Rule, and (5) make technical corrections to update the definition of health plan. In combination with the new penalties for violations of the HIPAA Privacy Rule, as provided for by the Recovery Act, a use or disclosure of genetic information in violation of the HIPAA Privacy Rule could result in a fine of $100 to $50,000 or more for each violation. ■

Interim final rule, 74 FR 51664, Oct. 7, 2009; Proposed rule, 74 FR 51698, Oct. 7, 2009; Health Care Compliance Reporter ¶700,234 and ¶730,075, respectively.

In the News

Revision of breach notification standard requested

The Chairman and ranking members of the House Committees on Energy and Commerce and Ways and Means have written a letter to HHS Secretary Sebelius requesting revision or repeal of the substantial harm standard that HHS has set for notification of individuals in the case of an unauthorized use or disclosure of personal health information (PHI). Section 13402 of the Recovery Act requires health care entities to notify individuals if there is an "unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information." In its August 24, 2009 interim final rule, "Breach Notification for Unsecured Protected Health Information," HHS interpreted the term "compromises" to include a substantial harm standard. According to the House, committee members specifically considered and rejected a harm standard due to concerns over the discretion that would be given to breaching entities, particularly with regard to determining something as subjective as harm from the release of PHI.

Letter from House Committees to HHS Secretary, Oct. 1, 2009

$7.6 million released for health care clinicians

HHS has announced 63 awards totaling more than $7.6 million to help states recruit new health care clinicians and alleviate debt. The funds are part of $500 million allotted to HHS' Health Resources and Services Administration by the Recovery Act to address work force shortages and diversity in the health professions. Eighteen grantees will receive $5.8 million under the State Loan Repayment Program which provides grants to states to fund loan repayment programs designed to increase the availability of primary health service providers in health professional shortage areas. Funds recipients incur a minimum two-year service obligation. In addition, 45 grantees will receive $1.8 million under the State Primary Care Office program to help recruit new National Health Service Corps (NHSC) clinicians. The funds will repay the qualifying student loans of primary care, medical, dental, and mental health clinicians who wish to practice, for a minimum of two years, in NHSC sites that treat underserved and uninsured people.

HHS Press Release, Sept. 30, 2009

2010 OIG work plan issued

The fiscal year 2010 edition of the Office of Inspector (OIG) General Work Plan, effective October 2009, describes ongoing and planned assignments. Targeted audits and evaluations by OIG continue to identify significant improper payments and problems in specific parts of the Medicare and Medicaid programs. These reviews have revealed payments for unallowable services, improper coding, and other types of improper payments. Other OIG reviews of CMS will include review of information systems and data security, the Children's Health Insurance Program, and investigative and legal activities related to CMS programs and operation. The second part of OIG's review includes review of public HHS programs, cross-cutting public health activities, and other departmentwide issues, including financial statement audits, financial accounting reviews, and the review of automated information systems. ■

FY 2010 OIG Work Plan, Oct. 1, 2009, Health Care Compliance Reporter, ¶540,055