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NCVHS rejects TCS extension; CMS issues guidance

by Jennifer Carsen, J.D., Contributing Editor

Although many healthcare providers will miss the October 16, 2003, implementation deadline for HIPAA's electronic data transactions and code set provisions, the National Committee on Vital and Health Statistics (NCVHS) has rejected the possibility of an extension. In response to concerns about the rapidly approaching deadline, the Centers for Medicare and Medicaid Services (CMS) has issued a guidance.

Deadline extension denied. In a letter to HHS Secretary Tommy G. Thompson, NCVHS noted that a "significant number" of covered entities would not meet the October deadline, for a variety of reasons. Many providers have been focused on complying with HIPAA's privacy protections, which became effective April 14, 2003, leaving little time for the upcoming October deadline. There is a general lack of knowledge about how to implement the nuts and bolts of HIPAA's electronic transactions and code set provisions, and some providers believe there will be another deadline extension, as there was last year. Finally, not all payers, providers, clearinghouses, and software vendors have made the necessary technical adjustments to electronically transmit or receive HIPAA-covered transactions.

Despite these obstacles, NCVHS opposes an extension to the October 16, 2003 deadline. With the possible exception of small providers, says NCVHS, most covered entities have made investments into complying with the deadline. Extending it would likely penalize them, while doing little to motivate noncompliant providers to take a new deadline seriously.

Flexible transition period. However, NCVHS is advocating flexibility in enforcement during a transition period not to extend beyond April 16, 2004. HHS enforcement could provide some flexibility by promoting good-faith compliance without limiting enforcement actions against entities not having taken steps to comply. During the transition period, a covered entity that was otherwise compliant would not be considered out of compliance if, for example, a payer accepts claims submitted in the HIPAA standard format, but with only the data elements that the payer requires to adjudicate the claim, or exchanges transactions with a provider in a pre-existing non-compliant electronic format.

To facilitate compliance, NCVHS advocates increased outreach by HHS to educate providers and payers about implementation requirements and provide technical assistance. Examples of additional outreach would include the development and dissemination of an implementation checklist and contingency planning

Letters to the Editor

The CCH Healthcare Compliance team welcomes comments or questions regarding articles published in the CCH Healthcare Compliance Letter. Send comments to Raio G. Krishnayya, Coordinating Editor, at krishnar@cch.com. For more information about the CCH Healthcare Compliance Portfolio visit our online store at http://health.cch.com.

assistance. NCVHS also recommends that HHS work with industry representatives to resolve uncertainties regarding the interpretation of the standards and the process for handling legacy claims—those in process before the October 16 deadline.

CMS guidance. Because of widespread concerns and confusion, CMS has released a guidance on compliance with the transaction regulations. In the guidance, CMS says "[t]he law is clear: October 16, 2003 is the deadline for covered entities to comply with HIPAA's electronic transaction and code set provisions." After that date, says CMS, covered entities may not conduct noncompliant transactions.

CMS will focus on voluntary compliance with HIPAA's electronic transactions and code set provisions. Enforcement efforts will be driven by complaints. When CMS receives a complaint about a covered entity, it will notify the entity in writing that a complaint has been filed. Following notification from CMS, the entity will have an opportunity to

- demonstrate compliance,
- document its good-faith efforts to comply with the standards, and/or
- submit a corrective action plan (CAP) to achieve compliance in an acceptable manner and time.

CMS says more information on CAPs will be forthcoming.

CMS will not impose a monetary penalty when a failure to comply is based on reasonable cause rather than willful neglect and the failure is cured within 30 days. HHS can also extend the period within which a covered entity may cure the noncompliance, "based on the nature and extent of the failure to comply."

Because transactions often require the participation of two covered entities, CMS acknowledges that noncompliance by one covered entity may put the other "in a difficult position." Accordingly, CMS will not impose penalties on covered entities that deploy contingencies in order to ensure the smooth flow of payments, if they have made reasonable and diligent efforts to become compliant or, in the case of health plans, to facilitate the compliance of their trading partners. Indications of good faith might include factors such as

- increased external testing with trading partners;
- lack of availability of, or refusal by, the trading partner(s) prior to the deadline to test the transaction(s) with the covered entity whose compliance is at issue; or
- in the case of a health plan, concerted efforts before and after the deadline to conduct outreach and make testing opportunities available to its provider community.

"There is a general lack of knowledge about how to implement the nuts and bolts of HIPAA's electronic transactions and code set provisions"

Covered entities are responsible for ensuring that electronic transactions are HIPAA-compliant, even if they use vendors, third-party administrators (TPAs), or clearinghouses. CMS has released a list of questions for covered entities to ask their vendors, TPAs, and clearinghouses to ensure that electronic transactions meet HIPAA standards by October 16. CMS notes that the HIPAA readiness of these third parties will directly affect a covered entity's HIPAA readiness.

In the remaining time before the October 16th deadline, HHS is encouraging health plans and providers to intensify their efforts toward achieving transaction and code set compliance. HHS is also urging health plans to assess the readiness of their provider communities to determine the need to implement contingency plans to maintain the flow of payments while continuing to work toward compliance.

A copy of the NCVHS letter can be found at http://ncvhs.hhs.gov/03062512.htm. ■

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Emergency patient transport arrangement cleared

by Geraldine S. Stroka, J.D., R.N., M.S.N.

A proposed arrangement to provide emergency transport for trauma patients by an ambulance service and a not-for-profit hospital implicated the Anti-kickback statute. However, the Office of Inspector General (OIG) permitted the plan. The OIG determined that the arrangement between the hospital and the ambulance service provided significant benefit to the rural community while posing minimal risk of federal healthcare program abuse.

Trauma mortality increased. The Department of Transportation of the state determined that patients suffering traumatic injuries in rural areas experienced increased mortality and disability when compared to other trauma patients across the state. According to the Department, the increased mortality for trauma patients resulted from:

(1) the great distance between properly equipped emergency rooms;
(2) inadequate ground ambulance coverage; and
(3) long response time by emergency personnel.

Under the state's trauma program, the transportation service is divided into areas governed by regional trauma councils (RAC). Membership in the RAC includes public safety agencies, hospitals and public and private ambulance service. These statistics prompted the hospital and the ambulance company to take action.

Joint helicopter program. The hospital and the ambulance company requesting this opinion issued a joint proposal to transport trauma victims. The two entities had no prior business relationships.

Under the proposed arrangement, the ambulance company would purchase, operate, staff, manage and maintain a helicopter equipped with a mobile intensive care unit. The hospital would provide, without charge:

(1) a helicopter landing pad adjacent to the hospital,
(2) quarters for the helicopter crew, and
(3) related utility and security services.

The landing pad and crew quarters would be available to any ambulance company transporting patients.

Anti-kickback statute implicated. Under the Anti-kickback statute, it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by federal healthcare programs, Soc. Sec. Act. §1128B(b). "Remuneration" under the Anti-kickback statute includes the transfer of anything of value, in cash or in-kind, directly or indirectly.

"This opinion re-emphasizes a position long-held by the OIG."

OIG's risk/benefit analysis. The OIG decided that this proposed helicopter transport arrangement presented a minimal risk of fraud and abuse to the federal healthcare programs, provided significant benefit to the community, and therefore permitted the plan. In making its determination, the OIG reasoned that the proposed arrangement:

(1) presented minimal risk of over utilization of federal healthcare programs because it dealt exclusively with emergency medical services;
(2) could not steer patients to the hospital because of the extensive regulations surrounding the referral pattern for the emergency transport of patients;
(3) was consistent with the emergency medical services and trauma care systems enacted to regulate and improve these systems; and
(4) would improve pre-hospital emergency and trauma care; thereby reducing the mortality and disability of this area's trauma patients.

Importance. This opinion re-emphasizes a position long-held by the OIG. The OIG continues to maintain that arrangements involving the provision of goods or services for nominal or at below market rates to actual or potential referral sources are suspect and may violate the Anti-kickback statute if one purpose is to induce or reward referrals of federal healthcare program business. ■

OIG Advisory Opinion 03-14, July 3, 2003, ¶150,211

Relationships between research funding agencies and individual researchers and their institutions

by Patricia Brent, J.D., M.P.H.

This is the third article covering compliance issues related to the provision of clinical research studies. The first article covered compliance issues related to claims submission, reimbursement and Anti-kickback concerns for clinical trials.[1] The second covered compliance issues related to the rights and safety of human participants in medical research studies.[2] This article addresses compliance issues associated with the relationship between the research sponsor or funding agency, and the medical researchers and their research institution, specifically institutional assurances of compliance and financial conflict of interest. The HIPAA privacy rule, as it applies to research programs, is also discussed. Reporting requirements, researcher misconduct, issues associated with funding accounts and accreditation programs will be addressed in a future article.

Institutional Assurances of Compliance

Institutional assurances of compliance are one of three important protections for human participants in medical research studies outlined in the federal regulations.[3] The others are: (1) informed consent, and (2) institutional review boards (IRBs). These protections emanate from ethical and medical care principles that evolved from the patient rights atrocities committed by the Nazis during World War II.[4] Notorious abuses of human participants in medical research studies also have occurred in the United States, notably the Tuskegee syphilis study of African-American males and the Willowbrook study of hepatitis B virus in institutionalized, learning disabled children.[5] They provided additional impetus for developing protections to safeguard human participants in medical research.

The Federal Policy for the Protection of Human Subjects in Medical Research (the Common Rule) requires that each institution "engaged" in federally-sponsored human subject research file an "Assurance of Compliance" for protecting human subjects.[6] This Assurance formalizes the institution's commitment to protect human subjects. The requirement for filing an Assurance applies both to the institution and to any collaborating "performance site" institutions. The federal Office of Human Research Protection (OHRP) is responsible for oversight of awards granted to research institutions and approves and oversees all Assurances. OHRP negotiates and approves the Assurances on the Department of Health and Human Services' (HHS) behalf. OHRP evaluates written complaints, allegations or evidence of noncompliance, no matter the source.

Under the Common Rule, institutions become "engaged" in human subject research whenever their employees or agents: (1) intervene or interact, for research purposes, with living individuals; or (2) obtain, release, or access individually identifiable private health information for research purposes.[7] Institutions are automatically considered "engaged" in human subject research whenever they receive a direct HHS award to support such research, even when all activities involving human subjects are carried out by a subcontractor or collaborator.[8] In such cases, the "awardee" institution bears ultimate responsibility for protecting human subjects and for ensuring that all collaborating institutions hold an OHRP-approved Assurance prior to initiating the research.

Assurances must describe the institution's means for complying with HHS regulations such as the protection of human subjects. The Assurance commits the institution, its researchers, and other personnel to full compliance with all applicable regulations.[9] Information required to be included in the written Assurance includes the following:[10]

- statement of principles governing the institution;
- designation and roster of the IRB; and
- IRB procedures for ensuring prompt reporting.

Activities required by the Assurance are guided by the ethical principles contained in the Belmont Report or other appropriate ethical standards recognized by federal departments and agencies that have adopted the Common Rule. Institutional responsibilities include:[11]

- bearing full responsibility for all research involving human participation covered under the Assurance;
- meeting all requirements for 45 CFR 46 or 21 CFR Parts 50 and 56 (for FDA-related research);
- designating one or more IRBs to review and approve all nonexempt research covered under the Assurance;

- providing sufficient space and staffing to support the IRB's review and record-keeping duties; and
- ensuring that appropriate Assurances and certificates of IRB review are submitted for all federally-sponsored research, including all participating performance sites.

These institutional assurances act, in essence, as a contract between the federal government and the institution and its researchers. In return for the institution and its researchers assuring compliance with federal regulations, the federal government agrees to fund the proposed research study. A violation of one or more of the terms of the Assurance is like a breach of contract. The federal government, through the OHRP, retains the ability to take corrective actions to remedy noncompliance with HHS regulations and to prevent reoccurrence of a violation. Usually, OHRP tailors its correction action requirements to each individual case. Recommended corrective actions may include:[12]

- requiring that an institution follow a specific "corrective action plan" designated by OHRP;
- requiring special reporting to OHRP from the institution;
- withdrawing approval of an institution's Assurance of Compliance, which results in the suspension of HHS support until an appropriate Assurance is approved;
- suspending, temporarily, or removing permanently an institution or investigator from specific projects; or
- declaring the institution or an individual researcher ineligible to participate in federally supported research (debarment), the most severe of the corrective actions that may be taken.

Consider the following actions to reduce the risk of noncompliance:

- Educate every key institutional participant in the research process on the terms of the Assurance: the IRB, senior management in the institution, the compliance officer responsible for research compliance (if in place), the principle investigator and the research study coordinator (if in place).
- Develop an action plan that includes monitoring each term of the Assurance and determine who is responsibility for monitoring the plan and reporting the results; and
- Develop a policy and procedure for correcting problems as they arise and are detected.

Financial Conflicts of Interest

There are increasing concerns that financial conflicts of interest in research, derived from financial relationships may affect the rights and safety of human participants in medical research studies.[13]Prudent stewardship of public monies that support medical research requires that careful steps be taken to ensure high quality outcomes. Conflicts of interest create at least a *perception* of bias on the part of researchers and their institutions and beg the question of whether these perceived (or actual) biases influence the outcome of decisions derived from the research. More importantly, any biased decision may put at risk the rights and safety of human participants in the research studies. Therefore, it is important to ensure that financial interests do not drive the analysis of data or the reporting of medical research and study results.

Both the Common Rule[14] (for publicly funded research) and FDA regulations[15] (for privately sponsored research) prohibit conflicts of interest from influencing the outcome of a clinical research study. Research studies that receive funding from a public health service agency, including the National Institutes of Health (NIH), must comply with regulations that require institutional officials to "manage" conflicts of interest issues.[16] The intent of conflict of interest policies is to promote "objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded by public monies will be biased by any conflicting financial interest of the research investigators or their institutions."[17]

In clinical research programs, financial conflict of interest issues may arise with members of the Institutional Review Board (IRB), physician-researchers, or the institution itself. According to federal guidelines, a conflict exists when the appropriate institutional official reasonably determines that a "significant financial interest" could directly and significantly affect the design, conduct, or reporting of the funded research.[18] To prevent an institution, members of its governing body or its employees from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain, each institution receiving Public Health Service (PHS) funds must have written policy guidelines on conflict of interest and the avoidance of conflicts.[19]These policies should reflect federal, state, and local regulations and must cover financial interests, gifts, gratuities and favors, nepotism and other areas, such as political participation and bribery. Each institution applying for HHS grants or contracts must, at a minimum, maintain written, enforced policies that:[20]

- comply with the regulations;
- inform each researcher of the regulation, the institution's policy and his/her reporting requirements;
- identify the institutional official(s) who determine whether a conflicting interest exists, and the person responsible for ensuring that appropriate actions be taken to manage, reduce or eliminate the conflict;
- provide for retention of records "for at least three years from the date of submission of final report" or as specified in 45 CFR 74.53(b);
- establish adequate enforcement mechanisms and sanctions; and

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- require that the institution certify it maintains written policies and procedures to identify, manage, reduce or eliminate conflicting interests.

It is important to understand that financial interests are not prohibited.[21] Indeed, most leaders in the medical research community, as well as government policy-makers concede that it is impossible to eliminate these financial relationships, especially given the long-standing practice of technology transfer between the federal government, academia, and the private sector.[22]Therefore, to the extent that financial relationships may affect the rights and welfare of human participants in medical research, "managing" these relationships has properly become the goal.

To this end, HHS has prepared the Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection."[23] This document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects and, if so, what actions could be considered to protect those subjects. The Guidance applies only to human subject research conducted or supported by HHS (e.g., NIH) or regulated by the Food and Drug Administration (FDA). It recommends consideration of approaches and methods for dealing with issues of financial interests under the HHS human research subject protections regulations (45 CFR 46 and 21 CFR parts 50 & 56). However, it does not address regulatory requirements designed to enhance data integrity and objectivity in research found in 42 CFR part 50, subpart F, 45 CFR part 94, and 21 CFR part 54. The guidance poses general considerations for evaluating financial relationships and their possible effects on human subjects. More detailed points for consideration are offered for institutions, IRBs and individual researchers.[24]

A number of non-governmental organizations have recently addressed the issue through published reports and guidelines. For example, both the Association of American Universities[25] and the American Association of Medical Colleges[26] recently have issued reports that include guidelines and recommended actions for reducing conflicts of interest in clinical research programs. Also, private medical societies, such as the American Society of Clinical Oncology, have published guidelines on financial conflicts of interest for their members to follow.[27] While beyond the scope of this article to fully discuss, below are a few of the most frequently cited guidelines:

- separating responsibility for financial decisions and research decisions;
- establishing procedures for disclosure of institutional, and individual researchers, financial relationships;
- establishing a conflict of interest committee;
- including individuals from outside the institution in the review and oversight of financial interests in research; and
- establishing policies regarding the types of relationships that may be held and the circumstances, including financial limitations, under which they may be held.

No matter which set of guidelines or guidances is followed, each provides an institution or the individual researcher with the opportunity to take actions that will decrease their risks of noncompliance and perceived biases.

HIPAA Privacy Rule in Research Settings

In addition to the ethical, health and safety protections required by federal statutes and regulations, the privacy and confidentiality of participants in clinical research studies must also be protected. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, effective since April 14, 2003, includes protections specific for participants in clinical research.[28] Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct vital research. Currently, most research involving human subjects operates under the Common Rule (45 CFR 46, Subpart A) or the FDA's human subject protection regulations (21 CFR Parts 50 & 56), which have some provisions for research. These human subject protections that apply to most federally funded and to some privately funded research, include protections to help ensure the privacy of participants and the confidentiality of information. The Privacy Rule builds on these existing federal protections. More importantly, the Privacy Rule creates equal standards of privacy protection for research governed by the existing federal human subject regulations and research that is not governed by these protections. Under HIPAA, healthcare providers who provide treatment to research participants must comply with the regulation.[29] Researchers who *do not* provide actual health care services, however, are not covered under the regulation. An effective research compliance program must address these regulations as a normal part of their monitoring and auditing processes. Some states also have patient privacy and confidentiality statutes and regulations that go beyond the protections provided by HIPAA and must also be considered.

HIPAA requires an authorization from patients for the purpose of using their personal health information (PHI) or for disclosure to another party for reasons other than treatment, payment or health care operations.[30]Covered entities may use and disclose PHI for research *if* they have proper authorization.[31]Only one authorization form is required for

all types of PHI uses and disclosures. If, however, disclosures are made for research purposes *without* the required authorization, HIPAA requires that providers account for those disclosures. And, because HIPAA authorization is considered as an important element in the informed consent process under the Common Rule, IRB approval is needed when the combined authorization form is used.[32] This can be an administrative burden. When a separate HIPAA authorization form is used for research purposes; however, IRB approval is not required.

In a change from the Proposed Rule, the final Privacy Rule provides a useful mechanism to ease the HIPAA burden for researchers: the limited data set.[33] Used in conjunction with a data use agreement, it allows a clinical researcher to send information containing some indirect patient identifiers to sponsors for research purposes. The data use agreement outlines both permitted and non-permitted uses for the data. A participant's name, address, and telephone number must be de-identified but the participant's zip code, city, and state can remain.[34]

Because recruitment of research participants is becoming more difficult, protection of participants' privacy is an important aspect to any successful clinical study. Moreover, since the outcome of research studies is so dependent on proper data analysis, it is vitally important that healthcare providers have the required authorizations in order to properly use and share their data. While a clinical research study sponsor, such as a medical device or pharmaceutical manufacturer, is *not* considered a business associate for the purpose of the HIPAA privacy rule, it is prudent for the sponsor to ensure the privacy of research participants. Using the limited data set is a means to accomplish this.

When PHI is used for the purpose of participant recruitment or for a pilot study, the HIPAA final rule requires researchers to obtain a waiver of authorization from their IRB in order to release participant pre-screening information. This information is subject to the"minimum necessary" requirements of HIPAA. However, if researchers do not want to go through the waiver process, then using "review preparatory to research" is a viable option, thus simplifying the IRB process. However, if the "review preparatory to research" option requires that the PHI cannot leave the covered entity.[35] This allows for the use of some information without requiring authorization.

Consider the following steps to ensure that your research program is HIPAA compliant:

- provide ongoing HIPAA training specially designed for researchers, the IRB and their staff to ensure that they understand both federal and state (if any) regulations;
- ensure that authorizations for the use of research data are appropriate and meet the regulatory standards; and
- outline in your sponsor agreements the anticipated data requirements and specify how that data will be gathered, stored, and disseminated and what actions must be met to properly meet regulatory standards.

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1 Patricia Brent, J.D., M.P.H., *Compliance Issues in Clinical Trials: Billing, Claims Submission and Anti-kickback Concerns*, CCH Healthcare Compliance Letter, Vol. 6, Issue 11, June 9, 2003.

2 Patricia Brent, J.D., M.P.H., *Compliance issues related to the protection and safety of human participants in medical research studies,* CCH Healthcare Compliance Letter, Vol. 6, Issue 16, August 18, 2003.

3 45 CFR 46, Subpart A.

4 G.J. Annas and M.A. Grondin, eds., *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation,* Oxford University Press, New York, 1992.

5 See *Tuskegee Syphilis Study Ad hoc Advisory Panel, Final Report,* U.S. Department of Health, Education and Welfare, Washington, D.C., 1973 and R.M. Veatch, *The Patient as Partner: A Theory of Human Experimentation Ethics,* Indiana University Press, Bloomington, IN, 1987.

6 45 CFR 46.103 (a).

7 45 CFR 46.102 (d),(f).

8 See Jan. 26, 1999 Memo from J. Thomas Puglisi, Ph.D., Director, Division of Human Subject Protection, OPRR, re: Engagement of Institutions in Research.

9 45 CFR 46.103 (a).

10 45 CFR 46.103 (b).

11 Id.

12 See December 4, 2000 Memo from Greg Koski, Ph.D., M.D., Director, Office of Human Research Protections re: Compliance Oversight Procedures.

13 *Draft Guidance: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection,* 68 FR 15456, Mar. 31, 2003.

14 45 CFR 46, Subpart A.

15 21 CFR parts 50 & 56.

16 42 CFR 50, Subpart F.

17 42 CFR 50.601.

18 42 CFR 50.605(a) and 42 CFR 50.603.

19 42 CFR 50.604.

20 Id.

21 *Draft Guidance: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection,* 68 FR 15456, Mar. 31, 2003.

22 Ezekiel J. Emanuel, M.D., Ph.D., and Daniel Steiner, L.L.B., *Institutional Conflict of Interest,* NEJM 332(4): 262-267, Jan. 26, 1995.

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Congressional report reveals healthcare race disparities

by Jennifer Carsen, J.D., Contributing Editor

A recent report by the Institute of Medicine, a branch of the National Academy of Sciences, found that racial and ethnic minority groups tend to receive a lower quality of health care than nonminorities, even when access-related factors such as income and insurance coverage are controlled.

Factors contributing to these disparities include physical, financial, and other types of access, and problems with provider-patient relationships, such as language barriers, cultural barriers, and provider bias. In response to a request by Senator Bill Frist (R-TN), the General Accounting Office (GAO) has released a report outlining the problem and possible responses to it.

A challenging problem. The GAO reviewed information from a variety of sources, including studies, journal articles, reports and interviews. It concluded that identifying promising solutions to racial and ethnic disparities in health care is challenging because current efforts are still in the early stages of implementation, evaluations and data are limited, and information on the nonfinancial causes of health care disparities is incomplete. Also, there is no overarching approach to address disparities; multiple approaches may be needed because groups and subgroups experience different disparities for different reasons.

Possible actions. However, the following approaches have been identified as possible ways for the federal government to address and help remedy disparities:

- **New demonstration projects.** Develop new demonstration projects in federal programs using the best available evidence to target areas of disparities and plan interventions. New demonstrations could incorporate solid evidence and data about disparities and interventions, as well as independent evaluation.
- **Expand current efforts** in programs and demonstration projects, such as the Center for Disease Control's REACH 2010 community-based coalitions. Currently, there are 42 community-based REACH 2010 coalitions across the country that target specific diseases among specific ethnic and racial groups.
- **Strengthen federal leadership** on disparities, including prompt dissemination of information for successful interventions to reduce or eliminate health care disparities. Stronger direction could include steps to develop additional interagency initiatives on disparities, ensure the collection and prompt dissemination of best practices, and promote the expansion of programs with demonstrated track records.
- **Collect complete and accurate data.** Collect racial and ethnic health care data in national surveys to better understand and target efforts to reduce health care disparities through steps such as insuring the inclusion of adequate numbers of minority participants. The Department of Health and Human Services (HHS) could contribute to these efforts by ensuring and supporting the inclusion of adequate numbers of minority participants in national surveys or conducting smaller-scale surveys of specific groups, and could help identify gaps in the understanding of disparities and interventions and using surveys to help fill them. ■

CCH Chicago Bureau, August 21, 2003

OTFL (cont.)

[23] *Draft Guidance: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection,* 68 FR 15456, Mar. 31, 2003.

[24] Id.

[25] Task Force on Research Accountability, Association of American Universities: *Report on Individual and Institutional Financial Conflicts of Interest,* October, 2001.

[26] Task Force on Financial Conflicts of Interest in Clinical Research, American Association of Medical Colleges: *Protecting subjects, Preserving Trust, Promoting Progress I (December 2001) and Promoting Progress II* (October, 2002).

[27] American Society for Clinical Oncology, *Guidelines on Financial Conflicts of Interest in Cancer Research,* April 29, 2003.

[28] *Final Rule,* 65 FR 82462, Dec. 28, 2000 and Modified Final Rule, 67 FR 6753182, Aug. 14, 2002.

[29] 45 CFR 164.501.

[30] 45 CFR 164.508.

[31] Id.

[32] 45 CFR 164.512 (i)(1)(ii).

[33] 45 CFR 164.514(e).

[34] 45 CFR 164.502 (d) and 45 CFR 164.514 (a)–(c).

[35] 45 CFR 164.512(i)(1)(ii).