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May 28,2002

John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street, *NW*
Washington, D.C. 20503

Re: Office of Management and Budget; Draft Report to Congress on the Costs and Benefits of Federal Regulations: Notice (FR 3/28/02)

Dear Mr. Morrall:

Thank you for the opportunity to provide the Office of Management and Budget public nominations of regulatory reforms. We appreciate the Bush Administration's efforts to make federal regulations less costly and less intrusive.

Regulations, which have an impact on the health care community, are in definite need of reform. Unfortunately, it is difficult to quantify the burdens that physicians face and the effect those burdens have on the practice of medicine. Many physician associations do not have the resources to conduct studies for an in-depth analysis and a financial impact of regulatory burdens.

The American Osteopathic Association (AOA) represents 47,000 osteopathic physicians nationwide, many of whom have small practices in **rural** and underserved areas. Osteopathic physicians represent 18% ***of*** all physicians practicing in small towns and rural areas with populations of 10,000 or less, and 22% of all physicians practicing in communities of 2,500 persons or less. The **AOA** is quite concerned about the ever-increasing regulatory burdens physicians face, especially physicians in such communities.

The Medicare Payment Advisory Commission issued a report to Congress in December 2001 on "Reducing Medicare Complexity and Regulatory Burden." The report noted that the most dramatic changes to the Medicare program occurred over the past several years, including mandates from the Balanced Budget Act of 1997, Balanced Budget Refinement Act of 1999, the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 and the Health Insurance Portability and Accountability Act of 1996. These laws translated into scores of new regulatory requirements for the health care provider community.

The physician and hospital communities must comply with regulatory requirements on the local, state and federal level. Without compatibility among these rules and regulations, providers face the daunting task of complying with regulations that oftentimes are inconsistent, contradictory and confusing.

As a result, the administrative costs of regulations oftentimes threaten to close the doors of solo physician practices and small group practices. To avoid this in the past, physicians increased their fees to non-Medicare patients, but that is no longer possible. Now to avoid closing a practice, physicians are forced to limit the number of Medicare patients they see or opt out of the program altogether. Patients, particularly in rural areas, must travel greater distances to find physicians who accept Medicare.

Many of the problems physicians face stem from poor information and a lack of qualified guidance from Medicare contractors as well as Centers for Medicare and Medicaid Services (CMS) regional offices. The General Accounting Office (GAO) reviewed contractor bulletins from 10 carriers. The GAO found that the bulletins contained lengthy discussions with overly technical and legalistic language that providers may find difficult to understand. The bulletins also omitted important information about mandatory billing procedures.

The GAO found that in 85% of its phone calls, the answers were incomplete or inaccurate. In addition, carrier Internet sites rarely met all CMS requirements and lacked user-friendly features such as site maps and search functions. We frequently hear such complaints from our membership. Our members also find that carriers at times are unwilling to put their communications with physician practices in writing. This behavior is unacceptable.

CMS regional offices also must be well versed in Medicare rules and regulations. A case in point:

In the mid 1990s, three osteopathic physicians in Oklahoma wanted to establish rural health clinics in the towns of Morrison (population 900), Yale (population 1,200), Pawnee (population 2,500) and Fairfax (population 1,800). They contacted CMS's regional office in Dallas, which guided them in establishing the federally designated rural health clinics. The regional office approved the clinics. Three years later, CMS headquarters in Baltimore contacted the doctors and told them they were over paid. CMS requested a repayment of $980,000 and in its effort to recover the money, all Part A Medicare payments were stopped.

It was ultimately determined that the regional office provided the wrong information. The rural health clinics were forced into bankruptcy. One clinic was shut down and the others are open on a part time basis – approximately one half to two half days a week. The error caused by the Federal government's regional office had devastating effects -- the doctors and patients paid the price.

The AOA applauds the Bush Administration's efforts to alleviate the regulatory burden facing the health care community. We believe the Department of Health and Human Services and the CMS are taking steps in the right direction to address the problems that have persisted for many years. More action is required.

- Congress should enact legislation that would protect health care professionals from future, unfunded federal mandates by requiring that Medicare payment rates better reflect the costs of mandates imposed on physicians and other health providers.

- Carriers and fiscal intermediaries need to be trained and educated to give appropriate guidance to physician practices. Physicians should not be punished when provided inaccurate information from their contractors, as is often the case.
- Congress and CMS must take into account regulatory requirements at the state and local level to develop federal rules that are compatible.

Enclosed for your perusal are copies of the MedPAC report and GAO statement. In addition, AOA has enclosed two nominations for regulatory reform as well as our previous comments on regulatory issues.

Thank you for considering our comments. We look forward to working with the Bush Administration on this and other issues of concern to the osteopathic medical profession.

Sincerely,

James E. Zini D.O.

James E. Zini, D.O.
AOA President

cc: President-Elect, AOA
Members, Board of Trustees, AOA
Chairman, Department of Government Affairs, AOA
Chairman and Members, Council on Federal Health Programs, AOA
Executive Director, AOA

Regulating Agency: HHS Office of Civil Rights (OCR)

Citation: Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency, 65 FR 52762

Authority: Title VI of the Civil Rights Act of 1964

Description of problem: The financial implications of complying with OCR's policy guidance standards could be devastating. For example, fees for a professional interpreter can run $40/hour or more with a two-hour minimum. If the interpreter fees end up costing more than the amount a physician actually is paid for a service, how is the physician expected to cover his/her costs? Concerns regarding costs and resources apply to the translation of written materials also, particularly when more than one foreign language is used.

According to the guidelines, language needs must be assessed by identifying the non-English languages likely to be encountered by reviewing census data, client utilization data, and data from schools and community organizations. In addition, a covered entity must identify the language needs of each LEP patient; points of contact; the resources; location and availability of those resources; and arrangements to access those resources.

Many physician practices, particularly in rural and underserved areas, are small businesses. Physicians and their staff already are stretched beyond their limits in complying with cumbersome rules and regulations, resulting in time and attention being taken from actual patient care. While the guidelines are supposed to improve access to care, these particular burdens could have the opposite impact.

Notification alone could be a costly and time-consuming endeavor. OCR's methods of notifying LEP persons regarding their right to language assistance and the availability of such assistance free of charge include: Use of language identification cards; post and maintain signs in regularly encountered languages; translation of application forms and other written material; uniform procedures for timely and effective telephone communication; and inclusion of statements about services available. OCR also calls for at least annual monitoring of language assistance programs.

The guidelines list several options for providing trained and competent interpreters such as hiring bilingual staff, staff interpreters, contracting with an outside interpreter service, arranging for voluntary services and arranging for a telephone service. In addition, the guidelines say "a recipient/covered entity must ensure that those persons it provides as interpreters are trained and demonstrate competency as interpreters."

Judging the competency of an interpreter may be a difficult task particularly when providers are not dealing with a common language. For example, Columbus, OH has a large concentration of Somalians. Physicians have had a difficult time finding appropriate interpreters for that population. If an error in interpretation occurs, who is to be held liable?

While OCR emphasizes that providers will have considerable flexibility, we must emphasize that current regulatory demands have physician practices at their breaking point. Having to

provide language services to LEP patients without any form of compensation will only create greater access problems for these patients.

We appreciate that the OCR will provide technical assistance to covered entities. However, state and federal government entities do not offer any funding to cover the costs of this compliance. No hospital, clinic or physician's office should face such a financial burden that could possibly force them to turn away patients or close their doors. If the state and federal governments are not willing to reimburse the physicians for these services, physician practices should be allowed to charge the patients for this added service.

Recommendation: *OCR should implement an immediate moratorium on the LEP regulation until the Administration can discuss the issue with all impacted parties to determine the best solution.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights; Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as It Affects Persons With Limited English Proficiency

AGENCY: Office for Civil Rights (OCR), HHS.

ACTION: Notice of republication of policy guidance with request for comment.

SUMMARY: The United States Department of Health and Human Services (HHS) is republishing for comment policy guidance on Title VI's prohibition against national origin discrimination as it affects limited English proficient (LEP) persons.

DATES: The guidance was effective August 30, 2000. Comments must be submitted on or before April 2, 2002. OCR will review all comments and will determine what modifications to the policy guidance, if any, are necessary.

ADDRESSES: Comments should be addressed to Deeana Jang with "Attention: LEP Comments," and should be sent to 200 Independence Avenue, SW. Room 506F, Washington, DC 20201. Comments may also be submitted by e-mail at *LEP.cornments@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Deeana Jang or Ronald Copeland at the Office for Civil Rights, Room 506F, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, addressed with "Attention: LEP Comments;" telephone toll-free number: 1–866–OCR–7748, or 202–619–0553; TDD: toll-free 1–800–537–7697. Arrangements to receive the policy in an alternative format may be made by contacting the named individuals.

SUPPLEMENTARY INFORMATION: The United States Department of Health and Human Services (HHS) is republishing for comment the policy guidance, "Title VI Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency" (the "guidance"). This guidance was originally published on August 30, 2000, and included a 60-day comment period. 65 FR 52762. However, pursuant to a memorandum issued by the United States Department of Justice on October 26, 2001, HHS is republishing this guidance and inviting public comment on the guidance. The United States Department of Justice memorandum is attached and can be found at: *http://www.usdoj.gov/crt/cor/lep/Oct26Memorandum.htm.*

The Secretary is interested in comments on all aspects of the guidance, including comments on the issues listed below. If you are raising a concern, please be as specific as possible.

(1) Have persons with limited English proficiency seeking health care or social services benefitted as a result of the guidance? If so, what have been the benefits? Please be specific about your experiences.

(2) Have persons with limited English proficiency faced challenges or problems in accessing health care or social services following issuance of the guidance? If so, what have been the challenges or problems? Please be specific about your experiences.

(3) Have health care or social services providers faced challenges or problems in providing these services to persons with limited English proficiency as a result of the guidance? If so, what have been the challenges or problems? Please be specific about your experiences. The Secretary is particularly interested in the experiences of small providers.

(4) Are there areas of the guidance that you believe need to be clarified or modified? If so, please explain what areas, why the area(s) need clarification or modification, and provide any suggestions for clarification or modification.

(5) Has the guidance been effective in identifying reasonable ways of providing services to individuals with limited English proficiency? What are some of the cost-effective ways that are used successfully to provide services for persons with limited English proficiency that are not included in the guidance? Again, the Secretary is particularly interested in the experiences of small providers.

(6) What technical assistance from the Office for Civil Rights (OCR) and other components of HHS would be most helpful to recipients/covered entities?

(7) In providing services to persons with limited English proficiency, what costs have health care or social services providers incurred in providing translation, interpreter, or other language services? Please be specific about your experiences. The Secretary is particularly interested in the experiences of small providers. If health care or social services providers have not yet provided translation, interpreter or other language services for persons with limited English proficiency, what costs are anticipated? Please provide the basis for your estimate.

(8) Some may assert that the guidance has materially assisted in achieving the goal of access to health or social services by limited English proficient individuals. Others may assert that the guidance has unintentionally had the opposite effect. Is there actual experience to support either view? Please describe.

(9) Based on your experience, does the guidance and/or OCR's application of the guidance in practice, strike the right balance with respect to the factors enunciated in the Department of Justice's October 26, 2001 memorandum: (1) The number or proportion of limited English proficient persons, (2) the frequency of contact with the program, (3) the nature and importance of the program, and (4) the resources available? Please note that these factors are discussed in greater detail in the Department of Justice memorandum, In particular, in considering the resources available, does the guidance and/or OCR's application of the guidance adequately factor in the costs of providing translation, interpreter or other language services to limited English proficient individuals, as well as the resources available to the recipient/covered entity?

The Department welcomes comments from the public on these and any other issues related to the guidance. Even if you have commented before on the guidance, you may have additional comments. In accordance with the instructions from the Department of Justice, the Department will review the guidance in light of the public comments received and the Department of Justice memorandum, and will determine what modifications to the guidance, if any, are necessary.

The text of the complete guidance document, including appendices, appears below.

Dated: January 28, 2002.

Robinsue Frohboese,

Principal Deputy and Acting Director, *Office for Civil Rights.*

Policy Guidance—Title VI Prohibition Against National Origin Discrimination **as** It **Affects** Persons With Limited English Proficiency

A. Background

English is the predominant language of the United States. According to the 1990 Census, English is spoken by 95% of its residents. Of those U.S. residents who speak languages other than English at home, the 1990 Census reports that 57% above the age of four speak English "well to very well."

The United States is also, however, home to millions of national origin minority individuals who are "limited

English proficient" (LEP). That is, they cannot speak, read, write or understand the English language at a level that permits them to interact effectively with health care providers and social service agencies. Because of these language differences and their inability to speak or understand English, LEP persons are often excluded from programs, experience delays or denials of services, or receive care and services based on inaccurate or incomplete information.

In the course of its enforcement activities, OCR has found that persons who lack proficiency in English frequently are unable to obtain basic knowledge of how to access various benefits and services for which they are eligible, such as the State Children's Health Insurance Program (SCHIP), Medicare, Medicaid or Temporary Assistance to Needy Families (TANF) benefits, clinical research programs, or basic health care and social services. For example, many intake interviewers and other front line employees who interact with LEP individuals are neither bilingual nor trained in how to properly serve an LEP person. As a result, the LEP applicant all too often is either turned away, forced to wait for substantial periods of time, forced to find his/her own interpreter who often is not qualified to interpret, or forced to make repeated visits to the provider's office until an interpreter is available to assist in conducting the interview.

The lack of language assistance capability among provider agency employees has especially adverse consequences in the area of professional staff services, such as health services. Doctors, nurses, social workers, psychologists, and other professionals provide vitally important services whose very nature requires the establishment of a close relationship with the client or patient that is based on empathy, confidence and mutual trust. Such intimate personal relationships depend heavily on the free flow of communication between professional and client. This essential exchange of information is difficult when the two parties involved speak different languages; it may be impeded further by the presence of an unqualified third person who attempts to serve as an interpreter.

Some health and social service providers have sought to bridge the language gap by encouraging language minority clients to provide their own interpreters as an alternative to the agency's use of qualified bilingual employees or interpreters. Persons of limited English proficiency must sometimes rely on their minor children to interpret for them during visits to a health or social service facility. Alternatively, these clients may be required to call upon neighbors or even strangers they encounter at the provider's office to act as interpreters or translators.

These practices have severe drawbacks and may violate Title VI of the Civil Rights Act of 1964. In each case, the impediments to effective communication and adequate service are formidable. The client's untrained "interpreter" is often unable to understand the concepts or official terminology he or she is being asked to interpret or translate. Even if the interpreter possesses the necessary language and comprehension skills, his or her mere presence may obstruct the flow of confidential information to the provider, This is because the client would naturally be reluctant to disclose or discuss intimate details of personal and family life in front of the client's child or a complete stranger who has no formal training or obligation to observe confidentiality.

When these types of circumstances are encountered, the level and quality of health and social services available to persons of limited English proficiency stand in stark conflict to Title VI's promise of equal access to federally assisted programs and activities. Services denied, delayed or provided under adverse circumstances have serious and sometimes life threatening consequences for an LEP person and generally will constitute discrimination on the basis of national origin, in violation of Title VI. Accommodation of these language differences through the provision of effective language assistance will promote compliance with Title VI. Moreover, by ensuring accurate client histories, better understanding of exit and discharge instructions, and better assurances of informed consent, providers will better protect themselves against *tort* liability, malpractice lawsuits, and charges of negligence.

Although OCR's enforcement authority derives from Title VI, the duty of health and human service providers to ensure that LEP persons can meaningfully access programs and services flows from a host of additional sources, including federal and state laws and regulations, managed care contracts, and health care accreditation organizations.[1] In addition, the duty to provide appropriate language assistance to LEP individuals is not limited to the health and human service context. Numerous federal laws require the provision of language assistance to LEP individuals seeking to access critical services and activities. For instance, the Voting Rights Act bans English-only elections in certain circumstances and outlines specific measures that must be taken to ensure that language minorities can participate in elections. See 42 U.S.C. Section 1973b(f)(1). Similarly, the Food Stamp Act of 1977 requires states to provide written and oral language assistance to LEP persons under certain circumstances. 42 U.S.C. Section 2020(e)(1) and (2). These and other provisions reflect the sound judgment that providers of critical services and benefits bear the responsibility for ensuring that LEP individuals can meaningfully access their programs and services.

OCR issued internal guidance to its staff in January 1998 on a recipient's obligation to provide language assistance to LEP persons. That guidance was intended to ensure consistency in OCR's investigation of LEP cases. This current guidance clarifies for recipient/covered entities and the public, the legal requirements under Title VI that OCR has been enforcing for the past 30 years.

This policy guidance is consistent with a Department of Justice (DOJ) directive noting that recipient/covered entities have an obligation pursuant to Title VI's prohibition against national origin discrimination to provide oral and written language assistance to LEP persons.[2] It is also consistent with a government-wide Title VI regulation issued by DOJ in 1976, "Coordination of Enforcement of Nondiscrimination in Federally Assisted Programs," 28 CFR part 42, subpart F, that addresses the circumstances in which recipient/covered entities must provide written language assistance to LEP persons.[3]

B. Legal Authority

1. Introduction

Over the last 30 years, OCR has conducted thousands of investigations and reviews involving language

[1] A description of these requirements is included as Appendix B to this policy guidance.

[2] The DOJ directive has been issued contemporaneously with this policy guidance.

[3] The DOJ coordination regulations at 28 CFR Section 42.405(d)(1) provide that "[w]here a significant number or proportion of the population eligible to be served or likely to be directly affected by a federally assisted program (e.g., affected by relocation) needs service *or* information in a language other than English in order effectively to be informed of or to participate in the program, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in appropriate languages to such persons. This requirement applies with regard to written material of the type which is ordinarily distributed *to* the public."

differences that impede the access of LEP persons to medical care and social services. Where the failure to accommodate language differences discriminates on the basis of national origin, OCR has required recipient/covered entities to provide appropriate language assistance to LEP persons. For instance, OCR has entered into voluntary compliance agreements and consent decrees that require recipients who operate health and social service programs to ensure that there are bilingual employees or language interpreters to meet the needs of LEP persons seeking services. OCR has also required these recipient/covered entities to provide written materials and post notices in languages other than English. *See Mendoza* v. *Lavine,* 412 F.Supp. 1105 (S.D.N.Y. 1976); and *Asociacion Mixta Progresista* v. *H.E.W.*, Civil Number C72–882 (N.D. Cal. 1976). The legal authority for OCR's enforcement actions is Title VI of the Civil Rights Act of 1964, the implementing regulations, and a consistent body of case law. The legal authority is described below.

2. Statute and Regulation

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. Section 2000d *et. seq.* states: "No person in the United States shall on the ground of race, color or national origin, be excluded from participation in, be denied the benefits of, *or* be subjected to discrimination under any program or activity receiving Federal financial assistance." Regulations implementing Title VI, provide in part at 45 CFR Section 80.3 (b):

(1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on ground of race, color, or national origin:

(i) Deny an individual any service, financial aid, or other benefit provided under the program;

[ii) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided *to* others under the program;

(2) A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program or the class of individuals to whom, or the situations in which such services, financial aid or other benefits, or facilities will be provided * * * *may not directly, or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuols to discrimination, because of their race, color or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives af the program with respect to individuals of a particular race, color or national origin.* (emphasis added).

3. Case Law

Extensive case law affirms the obligation of recipients of federal financial assistance to ensure that LEP persons can meaningfully access federal-assisted programs.

The U.S. Supreme Court, in *Lau* v. *Nichols,* 414 U.S. 563 (1974), recognized that recipients of Federal financial assistance have an affirmative responsibility, pursuant to Title VI, to provide LEP persons with meaningful opportunity to participate in public programs. In *Lau* v. *Nichols,* the Supreme Court ruled that a public school system's failure to provide English language instruction to students of Chinese ancestry who do not speak English denied the students a meaningful opportunity to participate in a public educational program in violation of Title VI of the Civil Rights Act of 1964.

The *Lau* decision affirmed the U.S. Department of Health, Education and Welfare's Policy Memorandum issued on May 25, 1970, titled "Identification of Discrimination and the Denial of Services on the Basis of National Origin," 35 FR 11,595. The memorandum states in part: "Where the inability to speak and understand the English language excludes national origin minority group children from effective participation in the educational program offered by a school district, the district must take affirmative steps to rectify the language deficiency in order to open its instructional program to these students."

As early as 1926, the Supreme court recognized that language rules were often discriminatory. In *Yu Cong Eng et.al.* v. *Trinidad, Collector* of *Internal Revenue,* 271 U.S. *500* (1926), the Supreme Court found that a Philippine Bookkeeping Act that prohibited the keeping of accounts in languages other than English, Spanish and Philippine dialects violated the Philippine Bill of Rights that Congress had patterned after the U.S. Constitution. The Court found that the Act deprived Chinese merchants, who were unable to read, write or understand the required languages, of liberty and property without due process.

In *Gutierrez* v. *Municipal* Court of *S.E. Judicial District,* 838 F.2d 1031, 1039 (9th Cir. 1988), *vacated as moot,* 490 U.S. 1016 (1989), the court recognized that requiring the use of English only is often used to mask national origin discrimination. Citing McArthur, *Worried About Something Else, 60* Int'l J. Soc. Language, 87, 90–91 (1986), the court stated that because language and accents are identifying characteristics, rules that have a negative effect on bilingual persons, individuals with accents, or non-English speakers may be mere pretexts for intentional national origin discrimination.

Another case that noted the link between language and national origin discrimination is *Garcia* v. *Gloor,* 618 F.2d 264 (5th Cir. 1980) *cert. denied,* 449 U.S. 1113 (1981). The court found that on the facts before it a workplace English-only rule did not discriminate *on* the basis of national origin since the complaining employees were bilingual. However, the court stated that "to a person who speaks only one tongue or to a person who has difficulty using another language other than the one spoken in his home, language might well be an immutable characteristic like skin color, sex or place of birth." *Id.* At 269.

The Fifth Circuit addressed language as an impermissible barrier to participation in society in *U.S.* v. *Uvalde Consolidated Independent School District,* 625 F2d 547 (5th Cir. 1980). The court upheld an amendment to the Voting Rights Act which addressed concerns about language minorities, the protections they were to receive, and eliminated discrimination against them by prohibiting English-only elections.

Most recently, the Eleventh Circuit in *Sandoval* v. *Hagan,* 197 F. 3d 484 (11th Cir. 1999), *petition for cert. filed,* May *30, 2000,* held that the State of Alabama's policy of administering a driver's license examination in English only was a facially neutral practice that had an adverse effect on the basis of national origin, in violation of Title VI. The court specifically noted the nexus between language policies and potential discrimination based on national origin. That is, in *Sandoval,* the vast majority of individuals who were adversely affected by Alabama's English-only driver's license examination policy were national origin minorities.

In the health and human service context, a recipient's failure to provide appropriate language assistance to LEP individuals parallels many of the fact situations discussed in the cases above and, as in those cases, may have an adverse effect on the basis of national origin, in violation of Title VI.

The Title VI regulations prohibit both intentional discrimination and policies and practices that appear neutral but have a discriminatory effect. Thus, a recipient/covered entity's policies or practices regarding the provision of benefits and services to LEP persons need not be intentional to be discriminatory, but may constitute a

violation of Title VI if they have an adverse effect on the ability of national origin minorities to meaningfully access programs and services. Accordingly, it is useful for recipient/covered entities to examine their policies and practices to determine whether they adversely affect LEP persons. This policy guidance provides a legal framework to assist recipient/covered entities in conducting such assessments.

C. Policy Guidance

1. Who Is Covered

All entities that receive Federal financial assistance from HHS, either directly or indirectly, through a grant, contract or subcontract, are covered by this policy guidance. Covered entities include (1) any state or local agency, private institution or organization, or any public or private individual that (2) operates, provides or engages in health, or social service programs and activities and that (3) receives federal financial assistance from HHS directly or through another recipient/covered entity. Examples of covered entities include but are not limited to hospitals, nursing homes, home health agencies, managed care organizations, universities and other entities with health or social service research programs, state, county and local health agencies, state Medicaid agencies, state, county and local welfare agencies, programs for families, youth and children, Head Start programs, public and private contractors, subcontractors and vendors, physicians, and other providers who receive Federal financial assistance from HHS.

The term Federal financial assistance to which Title VI applies includes but is not limited to grants and loans of Federal funds, grants or donations of Federal property, details of Federal personnel, or any agreement, arrangement or other contract which has as one of its purposes the provision of assistance. (*See,* 45 CFR section 80.13(f); and appendix A to the Title VI regulations, 45 CFR part 80, for additional discussion of what constitutes Federal financial assistance).

Title VI prohibits discrimination in any program or activity that receives Federal financial assistance. What constitutes a program or activity covered by Title VI was clarified by Congress in 1988, when the Civil Rights Restoration Act of 1987 (CRRA) was enacted. The CRRA provides that, in most cases, when a recipient/covered entity receives Federal financial assistance for a particular program or activity, all operations of the recipient/covered entity are covered by Title VI, not just the part of the program that uses the Federal assistance. Thus, all parts of the recipient's operations would be covered by Title VI, even if the Federal assistance is used only by one part.

2. Basic Requirements Under Title VI

A recipientlcovered entity whose policies, practices or procedures exclude, limit, or have the effect of excluding or limiting, the participation of any LEP person in a federally-assisted program on the basis of national origin may be engaged in discrimination in violation of Title VI. In order to ensure compliance with Title VI, recipient/covered entities must take steps to ensure that LEP persons who are eligible for their programs or services have meaningful access to the health and social service benefits that they provide. The most important step in meeting this obligation is for recipients of Federal financial assistance such as grants, contracts, and subcontracts to provide the language assistance necessary to ensure such access, at no cost to the LEP person.

The type of language assistance a recipient/covered entity provides to ensure meaningful access will depend on a variety of factors, including the size of the recipient/covered entity, the size of the eligible LEP population it serves, the nature of the program or service, the objectives of the program, the total resources available to the recipient/covered entity, the frequency with which particular languages are encountered, and the frequency with which LEP persons come into contact with the program. There is no "one size fits all" solution for Title VI compliance with respect to LEP persons. OCR will make its assessment of the language assistance needed to ensure meaningful access on a case by case basis, and a recipientlcovered entity will have considerable flexibility in determining precisely how to fulfill this obligation. OCR will focus on the end result—whether the recipient/covered entity has taken the necessary steps to ensure that LEP persons have meaningful access to its programs and services.

The key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively. The steps taken by a covered entity must ensure that the U P person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible. The covered entity must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider.

In enforcing Title VI and its application to LEP persons over the last 30 years, OCR has found that effective language assistance programs usually contain the four elements described in section three below. In reviewing complaints and conducting compliance reviews, OCR will consider a program to be in compliance when the recipient/covered entity effectively incorporates and implements these four elements. The failure to incorporate or implement one or more of these elements does not necessarily mean noncompliance with Title VI, and OCR will review the totality of the circumstances to determine whether LEP persons can meaningfully access the services and benefits of the recipient/covered entity.

3. Ensuring Meaningful Access to LEP Persons

(a) Introduction—The Four Keys to Title VI Compliance in the LEP Context

The key to providing meaningful access to benefits and services for LEP persons is to ensure that the language assistance provided results in accurate and effective communication between the provider and LEP applicant/client about the types of services and/or benefits available and about the applicant's or client's circumstances. Although HHS recipients have considerable flexibility in fulfilling this obligation, OCR has found that effective programs usually have the following four elements:

- —Assessment—The recipient/covered entity conducts a thorough assessment of the language needs of the population to be served;
- —Development of Comprehensive Written Policy on Language Access—The recipient/covered entity develops and implements a comprehensive written policy that will ensure meaningful communication;
- —Training of Staff—The recipient/covered entity takes steps to ensure that staff understands the policy and is capable of carrying it out; and
- —Vigilant Monitoring—The recipient/covered entity conducts regular oversight of the language assistance program to ensure that LEP persons meaningfully access the program.

The failure to implement one or more of these measures does not necessarily mean noncompliance with Title VI, and OCR will review the totality of the circumstances in each case. If implementation of one or more of these options would be so financially burdensome as to defeat the legitimate objectives of a recipientlcovered entity's program, or if there are equally effective alternatives for ensuring that LEP

persons have meaningful access to programs and services, OCR will not find the recipient/covered entity in noncompliance.

(b) Assessment

The first key to ensuring meaningful access is for the recipient/covered entity to assess the language needs of the affected population. A recipient/covered entity assesses language needs by:

- Identifying the non-English languages that are likely to be encountered in its program and by estimating the number of LEP persons that are eligible for services and that are likely to be directly affected by its program. This can be done by reviewing census data, client utilization data from client files, and data from school systems and community agencies and organizations:
- Identifying the language needs of each LEP patient/client and recording this information in the client's file:
- Identifying the points of contact in the program or activity where language assistance is likely to be needed:
- Identifying the resources that will be needed to provide effective language assistance:
- Identifying the location and availability of these resources; and
- Identifying the arrangements that must be made to access these resources in a timely fashion.

(c) Development of Comprehensive Written Policy on Language Access

A recipient/covered entity can ensure effective communication by developing and implementing a comprehensive written language assistance program that includes policies and procedures for identifying and assessing the language needs of its LEP applicants/clients, and that provides for a range of oral language assistance options, notice to LEP persons in a language they can understand of the right to free language assistance, periodic training of staff, monitoring of the program, and translation of written materials in certain circumstances.[4]

(1) Oral Language Interpretation — In designing an effective language assistance program, a recipient/covered entity develops procedures for obtaining and providing trained and competent interpreters and other oral language assistance services, in a timely manner, by taking some or all of the following steps:

- Hiring bilingual staff who are trained and competent in the skill of interpreting:
- Hiring staff interpreters who are trained and competent in the skill of interpreting:
- Contracting with an outside interpreter service for trained and competent interpreters;
- Arranging formally for the services of voluntary community interpreters who are trained and competent in the skill of interpreting;
- Arranging/contracting for the use of a telephone language interpreter service See Section 3(e)(2) for a discussion on "Competence of Interpreters."

The following provides guidance to recipient/covered entities in determining which language assistance options will be of sufficient quantity and quality to meet the needs of their LEP beneficiaries:

Bilingual Staff — Hiring bilingual staff for patient and client contact positions facilitates participation by LEP persons. However, where there are a variety of LEP language groups in a recipient's service area, this option may be insufficient to meet the needs of all LEP applicants and clients. Where this option is insufficient to meet the needs, the recipient/covered entity must provide additional and timely language assistance. Bilingual staff must be trained and must demonstrate competence as interpreters.

Staff Interpreters — Paid staff interpreters are especially appropriate where there is a frequent and/or regular need for interpreting services. These persons must be competent and readily available.

Contract Interpreters — The use of contract interpreters may be an option for recipient/covered entities that have an infrequent need for interpreting services, have less common LEP language groups in their service areas, or need to supplement their in-house capabilities on an as-needed basis. Such contract interpreters must be readily available and competent.

Community Volunteers — Use of community volunteers may provide recipient/covered entities with a cost-effective method for providing interpreter services. However, experience has shown that to use community volunteers effectively, recipient/covered entities must ensure that formal arrangements for interpreting services are made with community organizations so that these organizations are not subjected to ad hoc requests for assistance. In addition, recipient/covered entities must ensure that these volunteers are competent as interpreters and understand their obligation to maintain client confidentiality. Additional language assistance must be provided where competent volunteers are not readily available during all hours of service.

Telephone Interpreter Lines — A telephone interpreter service line may be a useful option as a supplemental system, or may be useful when a recipient/covered entity encounters a language that it cannot otherwise accommodate. Such a service often offers interpreting assistance in many different languages and usually can provide the service in quick response to a request. However, recipient/covered entities should be aware that such services may not always have readily available interpreters who are familiar with the terminology peculiar to the particular program or service. It is important that a recipient/covered entity not offer this as the only language assistance oprion except where other language assistance options are unavailable (*e.g.,* in a rural clinic visited by an LEP patient who speaks a language that is not usually encountered in the area).

(2) *Translation* of Written Materials — An effective language assistance program ensures that written materials that are routinely provided in English to applicants, clients and the public are available in regularly encountered languages other than English. It is particularly important to ensure that vital documents, such as applications, consent forms, letters containing important information regarding participation in a program (such as a cover letter outlining conditions of participation in a Medicaid managed care program), notices pertaining to the reduction, denial or termination of services or benefits, of the right to appeal such actions or that require a response from beneficiaries, notices advising LEP persons of the availability of free language assistance, and other outreach materials be translated into the non-English language of each regularly encountered LEP group eligible to be served or likely to be directly affected by the recipient/covered entity's program. However, OCR recognizes that each federally-funded health and social service program has unique characteristics. Therefore, OCR will collaborate with respective HHS agencies in determining which documents and information are deemed to be vital.

[4] The Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973 both provide similar prohibitions against discrimination on the basis of disability and require entities to provide language assistance such as sign language interpreters for hearing impaired individuals or alternative formats such as braille, large print or tape for vision impaired individuals. In developing a comprehensive language assistance program, recipient/covered entities should be mindful of their responsibilities under the ADA and Section 504 to ensure access to programs for individuals with disabilities.

As part of its overall language assistance program, a recipient must develop and implement a plan to provide written materials in languages other than English where a significant number or percentage of the population eligible to be served or likely to be directly affected by the program needs services or information in a language other than English to communicate effectively. 28 CFR Section 42.405(d)(1). OCR will determine the extent of the recipient/covered entity's obligation to provide written translation of documents on a case by case basis, taking into account all relevant circumstances, including the nature of the recipient/covered entity's services or benefits, the size of the recipient/covered entity, the number and size of the LEP language groups in its service area, the nature and length of the document, the objectives of the program, the total resources available to the recipient/covered entity, the frequency with which translated documents are needed, and the cost of translation.

One way for a recipient/covered entity to know with greater certainty that it will be found in compliance with its obligation to provide written translations in languages other than English is for the recipientlcovered entity to meet the guidelines outlined in paragraphs (A) and (B) below.

Paragraphs [A) and (B) outline the circumstances that provide a "safe harbor" for recipient/covered entities. A recipient/covered entity that provides written translations under these circumstances can be confident that it will be found in compliance with its obligation under Title VI regarding written translations.5 However, the failure to provide written translations under these circumstances outlined in paragraphs (A) and (B) will not necessarily mean noncompliance with Title VI.

In such circumstances, OCR will review the totality of the circumstances to determine the precise nature of a recipienticovered entity's obligation to provide written materials in languages other than English. If written translation of a certain document or set of documents would be so financially burdensome as to defeat the legitimate objectives of its program, or if there is an alternative means of ensuring that LEP persons have *meaningful* access to the information provided in the document [such as timely, effective oral interpretation of vita1 documents], OCR will not find the translation of written materials necessary for compliance with Title VI.

OCR will consider a recipienticovered entity to be in compliance with its Title VI obligation to provide written materials in non-English languages if

[A) The recipient/covered entity provides translated written materials, including vital documents, for each eligible LEP language group that constitutes ten percent or 3,000, whichever is less, of the population of persons eligible to be served or likely to be directly affected by the recipient/covered entity's program;[6]

(B) Regarding LEP language groups that do not fall within paragraph (A) above, but constitute five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be directly affected, the recipient/covered entity ensures that, at a minimum, vital documents are translated into the appropriate non-English languages of such LEP persons. Translation of other documents, if needed, can be provided orally: and

(C) Notwithstanding paragraphs (A) and (B) above, a recipient with fewer than 100 persons in a language group eligible to be served or likely to be directly affected by the recipient/covered entity's program, does not translate written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral translation of written materials.

The term "persons eligible to be served or likely to be directly affected" relates to the issue of what is the recipient/covered entity's service area for purposes of meeting its .Title VI obligation. There is no "one size fits all" definition of what constitutes "persons eligible to be served or likely to be directly affected" and OCR will address this issue on a case by case basis.

Ordinarily, persons eligible to be served or likely to be directly affected by a recipient's program are those persons who are in the geographic area that has been approved by a Federal grant agency as the recipient/covered entity's service area, and who either are eligible for the recipienticovered entity's benefits or services, or otherwise might be directly affected by such an entity's conduct. For example, a parent who might seek services for a child would be seen as likely to be affected by a recipient/covered entity's policies and practices. Where no service area has been approved by a Federal grant agency, OCR will consider the relevant service area for determining persons eligible to be served as that designated and/or approved by state or local authorities or designated by the recipient/covered entity itself, provided that these designations do not themselves discriminatorily exclude certain populations. OCR may also determine the service area to be the geographic areas from which the recipient draws, or can be expected to draw, clients/patients. The following are examples of how OCR would determine the relevant service areas when assessing who is eligible to be served or likely to-be affected-

* A complaint filed with OCR alleges that a private hospital discriminates against Hispanic and Chinese LEP patients by failing to provide such persons with language assistance, including written translations of consent forms. The hospital identifies its service area as the geographic area identified in its marketing plan. OCR determines that a substantial number of the hospital's patients are drawn from the area identified in the marketing plan and that no area with concentrations of racial, ethnic or other minorities is discriminatorily excluded from the plan. OCR is likely to accept the area identified in the marketing plan as the relevant service area.

• A state enters into a contract with a managed care plan for the provision of health services to Medicaid beneficiaries. The Medicaid managed care contract provides that the plan will serve beneficiaries in three counties. The contract is reviewed and approved by HHS. In determining the persons eligible to be served or likely to be affected, the relevant service area would be that designated in the contract.

As this guidance notes, Title VI provides that no person may be denied meaningful access to a recipient/covered entity's benefits and services, on the basis of national origin. To comply with the Title VI requirement, a recipientlcovered entity must ensure that LEP persons have meaningful access to and can understand information contained in program-related written documents. Thus, for

[5] The "safe harbor" provisions in paragraphs (A) and (B) below are not intended to establish numerical thresholds for when a recipient must translate documents. The numbers and percentages included in these provisions are based on the balancing of a number of factors, including OCR's experience in enforcing Title VI in the context of health and human services programs, and OCR's discussions with other Department agencies about experiences of their grant recipienticovered entities with language access issues.

[6] As noted above, vital documents include applications, consent forms, letters containing information regarding eligibility or participation criteria, and notices pertaining to reduction, denial or termination of services or benefits, that require a response from beneficiaries. and/or that advise of free language assistance. Large documents, such as enrollment handbooks, may not need to he translated in their entirety. However, vital information contained in large documents must be translated.

language groups that do not fall within paragraphs (A) and (B), above, a recipient can ensure such access by, at a minimum, providing notice, in writing, in the LEP person's primary language, of the right to receive free language assistance in a language other than English, including the right to competent oral translation of written materials, free of cost.

Recent technological advances have made it easier for recipient/covered entities to store translated documents readily. At the same time, OCR recognizes that recipient/covered entities in a number of areas, such as many large cities, regularly serve LEP persons from many different areas of the world who speak dozens and sometimes over 100 different languages. It would be unduly burdensome to demand that recipient/covered entities in these circumstances translate all written materials into dozens, if not more than 100 languages. As a result, OCR will determine the extent of the recipient/covered entity's obligation to provide written translations of documents on a case by case basis, looking at the totality of the circumstances.7

It is also important to ensure that the person translating the materials is well qualified. In addition, it is important to note that in some circumstances verbatim translation of materials may not accurately or appropriately convey the substance of what is contained in the written materials. An effective way to address this potential problem is to reach out to community-based organizations to review translated materials to ensure that they are accurate and easily understood by LEP persons.

(3) Methods for ***Providing*** Notice to *LEP* Persons—A vital part of a well-functioning compliance program includes having effective methods for notifying LEP persons regarding their right to language assistance and the availability of such assistance free of charge. These methods include but are not limited to:

—Use of language identification cards which allow LEP beneficiaries to identify their language needs to staff and for staff to identify the language needs of applicants and clients. To be effective, the cards (e.g., "I speak cards") must invite the LEP person to identify the language he/she speaks. This identification must be recorded in the LEP person's file;

—Posting and maintaining signs in regularly encountered languages other than English in waiting rooms, reception areas and other initial points of entry. In order to be effective, these signs must inform applicants and beneficiaries of their right to free language assistance services and invite them to identify themselves as persons needing such services;

—Translation of application forms and instructional, informational and other written materials into appropriate non-English languages by competent translators. For LEP persons whose language does not exist in written form, assistance from an interpreter to explain the contents of the document;

—Uniform procedures for timely and effective telephone communication between staff and LEP persons. This must include instructions for English-speaking employees to obtain assistance from interpreters or bilingual staff when receiving calls from *or* initiating calls to LEP persons; and

—Inclusion of statements about the services available and the right to free language assistance services, in appropriate non-English languages, in brochures, booklets, outreach and recruitment information and other materials that are routinely disseminated to the public.

(d) Training of Staff

Another vital element in ensuring that its policies are followed is a recipient/covered entity's dissemination of its policy to all employees likely to have contact with LEP persons, and periodic training of these employees. Effective training ensures that employees are knowledgeable and aware of LEP policies and procedures, are trained to work effectively with in-person and telephone interpreters, and understand the dynamics of interpretation between clients, providers and interpreters. It is important that this training be part of the orientation for new employees and that all employees in client contact positions be properly trained. Given the high turnover rate among some employees, recipienticovered entities may find it useful to maintain a training registry that records the names and dates of employees' training. Over the years, OCR has observed that recipient/covered entities often develop effective language assistance policies and procedures but that employees are unaware of the policies, or do not know how to, or otherwise fail to, provide available assistance, Effective training is one means of ensuring that there is not a gap between a recipient/covered entity's written policies and procedures, and the actual practices of employees who are in the front lines interacting with LEP persons.

(e) Monitoring

It is also crucial for a recipient/covered entity to monitor its language assistance program at least annually to assess the current LEP makeup of its service area, the current communication needs of LEP applicants and clients, whether existing assistance is meeting the needs of such persons, whether staff is knowledgeable about policies and procedures and how to implement them, and whether sources of and arrangements for assistance are still current and viable. One element of such an assessment is for a recipient/covered entity to seek feedback from clients and advocates. OCR has found that compliance with the Title VI language assistance obligation is most likely when a recipientlcovered entity continuously monitors its program, makes modifications where necessary, and periodically trains employees in implementation of the policies and procedures.

4. OCR's Assessment of Meaningful Access

The **failure** to take all of **the** steps outlined in Section C. 3, above, will not necessarily mean that a recipient/covered entity has failed to provide meaningful access to LEP clients. As noted above, **OCR** will make assessments on a case by case basis and will consider several factors in assessing whether the steps taken by a recipient/covered entity provide meaningful access. Those factors include the size of the recipientlcovered entity and of the eligible LEP population, the nature of the program or service, the objectives of the program, the total resources available, the frequency with which particular languages are encountered, and the frequency with which LEP persons come into contact with the program. The following are examples of

'For instance, a Medicaid managed **care** program that regularly encounters. or potentially will encounter on a regular basis, LEP persons who speak dozens or perhaps over 100 different languages, would not be required to translate the lengthy program brochure into every regularly encountered language. Rather, the recipientlcovered entity in these circumstances would likely be required to translate the written materials into the most frequently encountered languages. Regarding the remaining regularly encountered languages, the recipientlcovered entity would be required to ensure that the LEP person receives written notification in the appropriate non-English language of the right to free oral translation of the written materials. In addition, the recipientlcovered entity would frequently be required to provide written translations of vital documents that are short in length and pertain to important aspects of critical programs. such as a cover letter **that** outlines the terms and conditions of participation in a Medicaid managed care program, and/or contains time sensitive information about enrollment or continued participation.

how meaningful access will be assessed by OCR:

—A physician, a sole practitioner, has about 50 LEP Hispanic patients. He has a staff of two nurses and a receptionist, derives a modest income from his practice, and receives Medicaid funds. He asserts that he cannot afford to hire bilingual staff, contract with a professional interpreter service, or translate written documents. To accommodate the language needs of his LEP patients, he has made arrangements with a Hispanic community organization for trained and competent volunteer interpreters, and with a telephone interpreter language line, to interpret during consultations and to orally translate written documents. There have been no client complaints of inordinate delays or other service related problems with respect to LEP clients. Given the physician's resources, the size of his staff, and the size of the LEP population, OCR would find the physician in compliance with Title VI.

—A county TANF program, with a large budget, serves 500,000 beneficiaries. Of the beneficiaries eligible for its services, 3,500 are LEP Chinese persons, 4,000 are LEP Hispanic persons, 2000 *are* LEP Vietnamese persons and about 400 are LEP Laotian persons. The county has no policy regarding language assistance to LEP persons, and LEP clients are told to bring their own interpreters, are provided with application and consent forms in English and if unaccompanied by their own interpreters, must solicit the help of other clients or must return at a later date with an interpreter. Given the size of the county program, its resources, the size of the eligible LEP population, and the nature of the program, OCR would likely find the county in violation of Title VI and would likely require it to develop a comprehensive language assistance program that includes all *of* the options discussed in Section C. 3, above.

—A large national corporation receives TANF funds from a local welfare agency to provide computer training to TANF beneficiaries. Of the 2,000 clients that are trained by the corporation each month, approximately one-third are LEP Hispanic persons. The corporation has made no arrangements for language assistance and relies on bilingual Hispanic students in class to help LEP students understand the oral instructions and the written materials. Based on the size of the welfare agency and corporation, their budgets, the size of the LEP population, and the nature of the program, OCR would likely find both the welfare agency and the corporation in noncompliance with Title VI. The welfare agency would likely be found in noncompliance for failing to provide LEP clients meaningful access *to* its benefits and services through its contract with the corporation, and for failing to monitor the training program *to* ensure that it provided such access. OCR would likely also find the corporation in noncompliance for failing to provide meaningful access to LEP clients and would require it to provide them with both oral and written language assistance.

5. Interpreters

Two recurring issues in the area of interpreter services involve (a) the use of friends, family, or minor children as interpreters, and (b) the need *to* ensure that interpreters are competent, especially in the area of medical interpretation.

(a) *Use* of Friends, *Family* and Minor Children as Interpreters—A recipient/covered entity may expose itself to liability under Title VI if it requires, suggests, or encourages an LEP person to use friends, minor children, or family members as interpreters, as this could compromise the effectiveness of the service. Use of such persons could result in a breach of confidentiality or reluctance on the part of individuals to reveal personal information critical to their situations. In a medical setting, this reluctance could have serious, even life threatening, consequences. In addition, family and friends usually are not competent to act as interpreters, since they are often insufficiently proficient in both languages, unskilled in interpretation, and unfamiliar with specialized terminology.

If after a recipient/covered entity informs an LEP person of the right to free interpreter services, the person declines such services and requests the use of a family member or friend, the recipienticovered entity may use the family member or friend, if the use of such a person would not compromise the effectiveness of services or violate the LEP person's confidentiality. The recipient/covered entity should document the offer and declination in the LEP person's file. Even if an LEP person elects to use a family member or friend, the recipient/covered entity should suggest that a trained interpreter sit in on the encounter to ensure accurate interpretation.

(b) Competence of Interpreters—In order to provide effective services *to* LEP persons, a recipient/covered entity must ensure that it uses persons who are competent to provide interpreter services. Competency does not necessarily mean formal certification as an interpreter, though certification is helpful. On the other hand, competency requires more than self-identification as bilingual. The competency requirement contemplates demonstrated proficiency in both English and the other language, orientation and training that includes the skills and ethics of interpreting (e.g. issues of confidentiality), fundamental knowledge in both languages of any specialized terms, or concepts peculiar to the recipienticovered entity's program or activity, sensitivity to the LEP person's culture and a demonstrated ability to convey information in both languages, accurately. A recipienticovered entity must ensure that those persons it provides as interpreters are trained and demonstrate competency as interpreters.

6. Examples of Frequently Encountered Scenarios

Over the course of the past 30 years enforcing Title VI in the LEP context, OCR has observed a number of recurring problems. The following are examples of frequently encountered policies and practices that are likely to violate Title VI:

—A woman is brought to the emergency room of a hospital by her brother. The hospital has no language assistance services and requires her brother to interpret for her. She is too embarrassed to discuss her condition through her brother and leaves without treatment. Alternatively, she is forced to use her brother as the interpreter, who is untrained in medical terminology and through whom she refuses to discuss sensitive information pertaining to her medical condition.

—A health clinic uses a Spanish-speaking security guard who has no training in interpreting skills and is unfamiliar with medical terminology, as an interpreter for its Hispanic LEP patients. He frequently relays inaccurate information that results in inaccurate instructions to patients.

—A local welfare office uses a Vietnamese janitor to interpret whenever Vietnamese applicants or beneficiaries seek services or benefits. The janitor has been in America for six months, does not speak English well and is not familiar with the terminology that is used. He often

relays inaccurate information that results in the denial of benefits to clients.

—A state welfare agency does not advise a mother of her right to free language assistance and encourages her to use her eleven year old daughter to interpret for her. The daughter does not understand the terminology being used and relays inaccurate information to her mother whose benefits are jeopardized by the failure to obtain accurate information.

—A medical clinic uses a medical student as an interpreter based on her self-identification as bilingual. While in college, the student had spent a semester in Spain as an exchange student. The student speaks Spanish haltingly and must often ask patients to speak slowly and to repeat their statements. On several occasions, she has relayed inaccurate information that has resulted in misdiagnosis.

—A managed care plan calls the receptionist at an Ethiopian community organization whenever it or one of its providers needs the services of an interpreter for an Ethiopian patient. The plan instructs the receptionist to send anyone who is available as long as that person speaks English. Many of the interpreters sent to a provider either do not understand English well enough to interpret accurately or are unfamiliar with medical terminology. As a result, clients often misunderstand their rights and benefits.

—A local welfare office forces a Mandarin-speaking client seeking to apply for SCHIP benefits on behalf of her three year old child to wait for a number of hours (or tells the client to come back another day) to receive assistance because it cannot communicate effectively with her, and has no effective plan for ensuring meaningful communication. This results in a delay of benefits.

—An HMO that enrolls Medicaid beneficiaries instructs a non-English speaking client to provide his or her own interpreter services during all office visits.

—A health plan requires non-English speaking patients to pay for interpreter services.

D. Promising Practices

In meeting the needs of their LEP patients and clients, some recipient/covered entities have found unique ways of providing interpreter services and reaching out to the LEP community. As part of its technical assistance, OCR has frequently assisted, and will continue to assist, recipient/covered entities who are interested in learning about promising practices in the area of service to LEP populations. Examples of promising practices include the following:

Simultaneous Translation—One urban hospital is testing a state of the art medical interpretation system in which the provider and patient communicate using wireless remote headsets while a trained competent interpreter, located in a separate room, provides simultaneous interpreting services to the provider and patient. The interpreter can be miles away. This reduces delays in the delivery of language assistance, since the interpreter does not have to travel to the recipient/covered entity's facility. In addition, a provider that operates more than one facility can deliver interpreter services to all facilities using this central bank of interpreters, as long as each facility is equipped with the proper technology.

Language Banks—In several parts of the country, both urban and rural, community organizations and providers have created community language banks that train, hire and dispatch competent interpreters to participating organizations, reducing the need to have on-staff interpreters for low demand languages. These language banks are frequently nonprofit and charge reasonable rates. This approach is particularly appropriate where there is a scarcity of language services, or where there is a large variety of language needs.

Language Support Office—A state social services agency has established an "Office for Language Interpreter Services and Translation." This office tests and certifies all in-house and contract interpreters, provides agency-wide support for translation of forms, client mailings, publications and other written materials into non-English languages, and monitors the policies of the agency and its vendors that affect LEP persons.

Multicultural Delivery Project—Another county agency has established a "Multicultural Delivery Project" that is designed to find interpreters to help immigrants and other LEP persons to navigate the county health and social service systems. The project uses community outreach workers to work with LEP clients and can be used by employees in solving cultural and language issues. A multicultural advisory committee helps to keep the county in touch with community needs.

Pamphlets—A hospital has created pamphlets in several languages, entitled "While Awaiting the Arrival of an Interpreter." The pamphlets are intended to facilitate basic communication between inpatients/outpatients and staff. They are not intended to replace interpreters but may aid in increasing the comfort level of LEP persons as they wait for services.

Use of Technology—Some recipient/covered entities use their internet and/or intranet capabilities to store translated documents online. These documents can be retrieved as needed.

Telephone Information Lines—Recipient/covered entities have established telephone information lines in languages spoken by frequently encountered language groups to instruct callers, in the non-English languages, on how to leave a recorded message that will be answered by someone who speaks the caller's language.

Signage and Other Outreach—Other recipient/covered entities have provided information about services, benefits, eligibility requirements, and the availability of free language assistance, in appropriate languages by [a] posting signs and placards with this information in public places such as grocery stores, bus shelters and subway stations; (b) putting notices in newspapers, and on radio and television stations that serve LEP groups; (c) placing flyers and signs in the offices of community-based organizations that serve large populations of LEP persons; and (d) establishing information lines in appropriate languages.

E. Model Plan

The following is an example of a model language assistance program that is potentially useful for all recipient/covered entities, but is particularly appropriate for entities such as hospitals or social service agencies that serve a significant and diverse LEP population. This model plan incorporates a variety of options and methods for providing meaningful access to LEP beneficiaries:

- A formal written language assistance program;
- Identification and assessment of the languages that are likely to be encountered and estimating the number of LEP persons that are eligible for services and that are likely to be affected by its program through a review of census and client utilization data and data from school systems and community agencies and organizations;
- Posting of signs in lobbies and in other waiting areas, in several languages, informing applicants and clients of their right to free interpreter services and inviting them to identify themselves as persons needing language assistance;
- Use of "I speak" cards by intake workers and other patient contact

personnel so that patients can identify their primary languages;

• Requiring intake workers to note the language of the LEP person in his/her record so that all staff can identify the language assistance needs of the client:

• Employment of a sufficient number of staff, bilingual in appropriate languages, in patient and client contact positions such as intake workers, caseworkers, nurses, doctors. These persons must be trained and competent as interpreters;

• Contracts with interpreting services that can provide competent interpreters in a wide variety of languages, in a timely manner;

• Formal arrangements with community groups for competent and timely interpreter services by community volunteers;

• An arrangement with a telephone language interpreter line;

• Translation of application forms, instructional, informational and other key documents into appropriate non-English languages. Provision of oral interpreter assistance with documents, for those persons whose language does not exist in written form;

• Procedures for effective telephone communication between staff and LEP persons, including instructions for English-speaking employees to obtain assistance from bilingual staff or interpreters when initiating or receiving calls from LEP persons;

• Notice to and training of all staff, particularly patient and client contact staff, with respect to the recipient/covered entity's Title VI obligation to provide language assistance to LEP persons, and on the language assistance policies and the procedures to be followed in securing such assistance in a timely manner;

• Insertion of notices, in appropriate languages, about the right of LEP applicants and clients to free interpreters and other language assistance, in brochures, pamphlets, manuals, and other materials disseminated to the public and to staff;

• Notice to the public regarding the language assistance policies and procedures, and notice to and consultation with community organizations that represent LEP language groups, regarding problems and solutions, including standards and procedures for using their members as interpreters;

• Adoption of a procedure for the resolution of complaints regarding the provision of language assistance; and for notifying clients of their right to and how to file a complaint under Title VI with HHS.

• Appointment of a senior level employee to coordinate the language assistance program, and ensure that there is regular monitoring of the program.

F. Compliance *and* Enforcement

The recommendations outlined above are not intended to be exhaustive. Recipient/covered entities have considerable flexibility in determining how to comply with their legal obligation in the LEP setting, and are not required to use all of the suggested methods and options listed. However, recipient/covered entities must establish and implement policies and procedures for providing language assistance sufficient to fulfill their Title VI responsibilities and provide LEP persons with meaningful access to services.

OCR will enforce Title VI as it applies to recipient/covered entities' responsibilities to LEP persons through the procedures provided for in the Title VI regulations. These procedures include complaint investigations, compliance reviews, efforts to secure voluntary compliance, and technical assistance.

The Title VI regulations provide that OCR will investigate whenever it receives a complaint, report or other information that alleges or indicates possible noncompliance with Title VI. If the investigation results in a finding of compliance, OCR will inform the recipient/covered entity in writing of this determination, including the basis for the determination. If the investigation results in a finding of noncompliance, OCR must inform the recipient/covered entity of the noncompliance through a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance, and must attempt to secure voluntary compliance through informal means. If the matter cannot be resolved informally, OCR must secure compliance through (a) the termination of Federal assistance after the recipient/covered entity has been given an opportunity for an administrative hearing, (b) referral to DOJ for injunctive relief or other enforcement proceedings, or (c) any other means authorized by law.

As the Title VI regulations set forth above indicate, OCR has a legal obligation to seek voluntary compliance in resolving cases and cannot seek the termination of funds until it has engaged in voluntary compliance efforts and has determined that compliance cannot be secured voluntarily. OCR will engage in voluntary compliance efforts, and will provide technical assistance to recipients at all stages of its investigation. During these efforts to secure voluntary compliance, OCR will propose reasonable timetables for achieving compliance and will consult with and assist recipientlcovered entities in exploring cost effective ways of coming into compliance, by sharing information on potential community resources, by increasing awareness of emerging technologies, and by sharing information on how other recipient/covered entities have addressed the language needs of diverse populations.

OCR will focus its compliance review efforts primarily on larger recipient/covered entities such as hospitals, managed care organizations, state agencies, and social service organizations, that have a significant number or percentage of LEP persons eligible to be served, or likely to be directly affected, by the recipient/covered entity's program. Generally, it has been the experience of OCR that in order to ensure compliance with Title VI, these recipient/covered entities will be expected to utilize a wider range of the language assistance options outlined in section C. 3, above.

The fact that OCR is focusing its investigative resources on larger recipient/covered entities with significant numbers or percentages of LEP persons likely to be served or directly affected does not mean that other recipient/covered entities are relieved of their obligation under Title VI, or will not be subject to review by OCR. In fact, OCR has a legal obligation under HHS regulations to promptly investigate all complaints alleging a violation of Title VI. All recipient/covered entities must take steps to overcome language differences that result in barriers and provide the language assistance needed to ensure that LEP persons have meaningful access to services and benefits. However, smaller recipient/covered entities—such as sole practitioners, those with more limited resources, and recipient/covered entities who serve small numbers of LEP persons on an infrequent basis—will have more flexibility in meeting their obligations to ensure meaningful access for LEP persons.

In determining a recipient/covered entity's compliance with Title VI, OCR's primary concern is to ensure that the recipient/covered entity's policies and procedures overcome barriers resulting from language differences that would deny LEP persons a meaningful opportunity to participate in and access programs, services and benefits. A recipient/covered entity's appropriate

use of the methods and options discussed in this policy guidance will be viewed by OCR as evidence of a recipient/covered entity's willingness to comply voluntarily with its Title VI obligations.

G. Technical Assistance

Over the past 30 years, OCR has provided substantial technical assistance to recipienticovered entities, and will continue to be available to provide such assistance to any recipienticovered entity seeking to ensure that it operates an effective language assistance program. In addition, during its investigative process, OCR is available to provide technical assistance to enable recipient/covered entities to come into voluntary compliance.

H. Attachments

Appendix A is a summary, in question and answer format, of a number of the critical elements of this guidance. The purpose of the summary is to assist recipient/covered entities further in understanding this guidance and their obligations under Title VI to ensure meaningful access to LEP persons. Appendix B is a list of numerous provisions, including but not limited to Federal and state laws and regulations, requiring the provision of language assistance to LEP persons in various circumstances. This list is not exhaustive, and is not limited to the health and human service context.

Appendix A Questions and Answers Regarding the Office for Civil Rights Policy Guidance on the Title VI Prohibition Against National Origin Discrimination as it Affects Persons With Limited English Proficiency

1. Q. What *Is* the Purpose of *the Guidance on* Language Access Released *by* the Office *for* Civil Rights *(OCR) of the U.S.* Department of Health and Human *Services (HHS)?*

A. The purpose of the Policy Guidance is two-fold: First. *to* clarify the responsibilities of providers of health and social services who receive Federal financial assistance from HHS, and assist them in fulfilling their responsibilities to Limited English Proficient (LEP) persons, pursuant to Title VI of the Civil Rights Act of 1964; and second, to clarify to members of the public that health and social service providers must ensure that LEP persons have meaningful access to their programs and services.

2. Q. What *Does* the Policy Guidance *Do?*

A. The policy guidance does the following:

- Reiterates the principles of Title VI with respect to LEP persons.
- Discusses the policies, procedures and other steps that recipients can take to ensure meaningful access to their program by LEP persons.
- Clarifies that failure to take one or more of these steps does not necessarily mean noncompliance with Title VI.
- Provides that OCR will determine compliance on a case by case basis, and that such assessments will take into account the size of the recipient, the size of the LEP population, the nature of the program, the resources available, and the frequency of use by LEP persons.
- Provides that small providers and recipient/covered entities with limited resources, will have a great deal of flexibility in achieving compliance.
- Provides that OCR will provide extensive technical assistance as needed by recipient/covered entities.

3. Q. *Does* the Guidance Impose *New* Requirements on *Recipient/Covered Entities?*

A. No. Since its enactment, Title VI of the Civil Rights Act of 1964 has prohibited discrimination on the basis of race, color or national origin in any program or activity that receives federal financial assistance. In order to avoid violating Title VI, recipient/covered entities must ensure that they provide LEP persons meaningful opportunity to participate in their programs, services and benefits. Over the past three decades, OCR has conducted thousands of investigations and reviews involving language differences that affect the access of LEP persons to medical care and social services. Where such language differences prevent meaningful access on the basis of national origin, the law requires that recipienticovered entities provide oral and written language assistance at no cost to the recipient. This guidance synthesizes the legal requirements that have been on the books and that OCR has been enforcing for over three decades.

4. Q. *Who Is* Covered *by* th& *Guidance?*

A. Covered entities include any state or local agency, private institution or organization, or any public or private individual that (1) operates, provides or engages in health, or social service programs and activities, and (2) receives Federal financial assistance from HHS directly or through another recipient/covered entity. Examples of covered entities include but are not limited to hospitals, nursing homes, home health agencies, managed care organizations, universities and other entities with health or social service research programs; state, county and local health agencies; state Medicaid agencies; state, county and local welfare agencies: programs for families, youth and children; Head Start programs; public and private contractors, subcontractors and vendors; physicians; and other providers who receive Federal financial assistance from HHS.

5. Q. *How Does* the Guidonce Affect Small Practitioners and Providers?

A. The key to providing meaningful access for LEP persons is to ensure that the relevant circumstances of the LEP person's situation can be effectively communicated to the service provider and the LEP person is able to understand the services and benefits available and is able to receive those services and benefits for which he or she is eligible in a timely manner. Small practitioners and providers will have considerable flexibility in determining precisely how to fulfill their obligations to ensure meaningful access for persons with limited English proficiency. OCR will assess compliance on a case by case basis and will take into account the size of the recipienticovered entity, the size of the eligible LEP population it serves, the nature of the program or service, the objectives of the program, the total resources available to the recipient/covered entity, the frequency with which languages are encountered and the frequency with which LEP persons come into contact with the program. There is no "one size fits all" solution for Title VI compliance with respect to LEP persons.

In other words, OCR will focus on the end result, that is, whether the small practitioner or provider has taken steps, given the factors that will be considered by OCR, to ensure that the LEP persons have access to the programs and services provided by the physician. OCR will continue to be available to provide technical assistance to any physician seeking to ensure that s/he operates an effective language assistance program.

For example: A physician, a sole practitioner, has about 50 LEP Hispanic patients. He has a staff of two nurses and a receptionist derives a modest income from his practice, and receives Medicaid funds. He asserts that he cannot afford to hire bilingual staff, contract with a professional interpreter service, or translate written documents. To accommodate the language needs of his LEP patients he has made arrangements with a Hispanic community organization for trained and competent volunteer interpreters and with a telephone interpreter language line, to interpret during consultations and to orally translate written documents. There have been no client complaints of inordinate delays or other service related problems with respect to LEP clients. Given the physician's resources, the size of his staff, and the size of the LEP population, OCR would find the physician in compliance with Title VI.

6. Q. The Guidonce Identifies Some *Specific* Circumstances Under *Which OCR* Will Consider a Program To Be *in Compliance* With Its Obligation Under *Title VI* To *Provide* Written Materials *in* Languages Other *Than* English. Does This Mean That a *Recipient/* Covered Entity *Will Be Considered* Out of Compliance With Title *VI* if Its Program *Does Not Fall* Within These Circumstances?

A. No. The circumstances outlined in the guidance are intended to provide a *"safe* harbor" for recipients who desire greater certainty with respect to their obligations to provide written translations. Thus, a recipient/covered entity whose policies and practices fall within these circumstances can be confident that, with respect to written translations, it will be found in compliance with Title VI. However, the failure to fall within the "safe harbors" outlined in the guidance does not necessarily mean that a recipienticovered entity is not in compliance with Title VI. In such circumstances, OCR will review the totality of circumstances to determine the precise nature of a recipient/covered entity's obligation to provide written materials in languages *other* than English. If

translation of a certain document or set of documents would be so financially burdensome as to defeat the legitimate objectives of its program, or if there is an alternative means of ensuring that LEP persons have meaningful access to the information provided in the document (such as timely, effective oral interpretation of vital documents), OCR will likely not find the translation necessary for compliance with Title VI.

7. Q. The Guidance Makes Reference to "Vital Documents" and Notes That, in Certain Circumstances, a Recipient/Covered Entity May Have To Translate *Such* Documents *Into* Other Languages. *What* Is a *Vital* Document?

A. Given the wide array of programs and activities receiving HHS financial assistance, we do not attempt to identify vital documents and information with specificity in each program area. Rather, a document or information should be considered vital if it contains information that is critical for accessing the federal fund recipient's services and/or benefits, or is required by law. Thus, vital documents include, but are not limited to, applications, consent forms, letters and notices pertaining to the reduction, denial or termination of services or benefits, letters or notices that require a response from the beneficiary or client, and documents that advise of free language assistance. OCR will also collaborate with respective HHS agencies in determining which documents and information are deemed to be vital within a particular program.

8. Q. Will *Recipient/Covered* Entities Have To Translate Large Documents *Such* as Managed Care Enrollment *Han*dbooks?

A. Not necessarily. As part of its overall language assistance program, a recipient must develop and implement a plan to provide written materials in languages other than English where a significant number or percentage of the population eligible to be served, or likely to be directly affected by the program, needs services or information in a language other than English to communicate effectively. OCR will assess the need for written translation of documents and vital information contained in larger documents on a case by case basis, taking into account all relevant circumstances, including the nature of the recipienticovered entity's services or benefits, the size of the recipient/covered entity, the number and size of the LEP language groups in its service area, the nature and length of the document, the objectives of the program, the total resources available to the recipient/covered entity, the frequency which particular languages are encountered and the frequency with which translated documents are needed and the cost of translation. Depending on these circumstances, large documents, such as enrollment handbooks, may not need to be translated or may not need to be translated in their entirety. For example, a recipient/covered entity may be required to provide written translations of vital information contained in larger documents, but may not have to translate the entire document, to meet its obligations under Title VI.

9. Q. May a *Recipient/Covered Entity* Require an LEP *Person* To Use a Family Member or o Friend *us His* or *Her* Interpreter?

A. No. OCR's policy requires the recipient/covered entity to inform the LEP person of the right to receive free interpreter services first and permits the use of family and friends only after such offer of assistance has been declined and documented. Our policy regarding the use of family and friends as interpreters is based on over three decades of experience with Title VI. Although OCR recognizes that some individuals may be uncomfortable having a stranger serve as an interpreter, especially when the situation involves the discussion of very personal or private matters, it is our experience that family and friends frequently are not competent to act as interpreters, since they may be insufficiently proficient in both languages, untrained and unskilled as interpreters, and unfamiliar with specialized terminology. Use of such persons also may result in breaches of confidentiality or reluctance on the part of the individual to reveal personal information critical to their situations. These concerns are even more pronounced when the family member called upon to interpret is a minor. In other words, when family and friends are used, there is a grave risk that interpretation may not be accurate or complete. In medical settings, in particular, this can result in serious, even life threatening consequences.

10. Q. How Does *Low Health Literacy, Non-*Literacy, *Non-*Written Languages, Blindness and Deafness Among LEP Populations Affect the *Responsibilities* of Federal Fund Recipients?

A. Effective communication in any language requires **an** understanding of the literacy levels of the eligible populations. However, literacy generally is a program operations issue rather than a Title VI issue. Where a LEP individual has a limited understanding of health matters or cannot read, access to the program is complicated by factors not directly related to national origin or language. Under these circumstances, a recipient/covered entity should provide remedial health information to the same extent that it would provide such information to English-speakers. Similarly, a recipient/covered entity should assist LEP individuals who cannot read in understanding written materials as it would non-literate English-speakers. A non-written language precludes the translation of documents, but does not affect the responsibility of the recipient to communicate the vital information contained in the document or to provide notice of the availability of oral translation. Section 504 of the Rehabilitation Act of 1973 requires that federal fund recipients provide sign language and oral interpreters for people who have hearing impairments and provide materials in alternative formats such as in large print, braille or on tape for individuals with impairments. The Americans with Disabilities Act imposes similar requirements on health and human service providers.

11. Q. Can OCR Provide Help to *Recipient/* Covered Entities Who Wish To Come Into Compliance With Title *VI?*

A. Absolutely. For over three decades, OCR has provided substantial technical assistance to recipient/covered entities who are seeking to ensure that LEP persons can meaningfully access their programs or services. Our regional staff is prepared to work with recipients to help them meet their obligations under Title VI. As part of its technical assistance services, OCR can help identify best practices and successful strategies used by other federal fund recipients. identify sources of federal reimbursement for translation services, and point providers to other resources.

12. Q. *How* Will OCR Enforce Compliance *by Recipient/Covered* Entities *With* the LEP Requirements of Title *VI?*

A. OCR will enforce Title VI as it applies to recipient/covered entities through the procedures provided for in the Title VI regulations. The Title VI regulations provide that OCR will investigate whenever it receives a complaint, report, or other information that alleges or indicates possible noncompliance with Title VI. If the investigation results in a finding of compliance, OCR will inform the recipient/covered entity in writing of this determination, including the basis for the determination. If the investigation results in a finding of noncompliance, OCR must inform the recipient/covered entity of the noncompliance through a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance. By regulation, OCR must attempt to secure voluntary compliance through informal means. In practice, OCR has been quite successful in securing voluntary compliance and will continue these efforts. If the matter cannot be resolved informally, OCR must secure compliance through (a) the termination of Federal assistance after the recipient/covered entity has been given an opportunity for an administrative hearing, (b) referral to DOJ for injunctive relief or other enforcement proceedings, or (c) any other means authorized by law.

13. Q. Does Issuing This Guidance Mean That *OCR* Will Be Changing How *it* Enforces Compliance With Title *VI?*

A. No. How OCR enforces Title VI is governed by the Title VI implementing regulations. The methods and procedures used to investigate and resolve complaints, and conduct compliance reviews, have not changed.

14. Q. What *Is HHS* Doing *To* Ensure *It Is Following* the Guidance *It Is* Giving to States *and* Others?

A. Although legally, federally conducted programs and activities are not subject to Title VI, HHS recognizes the importance of ensuring that its programs and services are accessible to LEP persons. To this end, HHS has established a working group to assess how HHS itself is providing language access. Currently, agencies across HHS have taken a number of important steps to ensure that their programs and services are accessible to

LEP persons. For example, a number of agencies have translated important consumer materials into languages other than English. Also, several agencies have launched Spanish language web sites. In order to ensure that all HHS federally conducted programs and activities are accessible to LEP persons, the Secretary has directed the working group to develop and implement a Department-wide plan for ensuring LEP persons meaningful access to HHS programs. This internal HHS initiative was begun prior to the President's August 11, 2000, Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency". The Executive Order requires Federal Agencies to develop and implement a system for ensuring LEP persons meaningful access to their federally-conducted programs. It also requires agencies to issue guidance to their recipients on the recipients' obligations to provide LEP persons meaningful access to their federally-assisted programs. HHS is a step ahead on each of the obligations outlined in the Executive .Order.

Appendix B: Selected Federal and State Laws and Regulations Requiring Language Assistance

Federal Laws and Regulations

Federal laws that recognize the need for language assistance include:

1. The Voting Rights Act, which bans English-only elections and prescribes other remedial devices to ensure nondiscrimination against language minorities;[1]

2. The Food Stamp Act of 1977, which requires states to provide written and oral language assistance to LEP persons under certain circumstances; [2]

3. Judicial procedure laws that require the use of certified or otherwise qualified interpreters for LEP parties and witnesses, at the government's expense, in certain proceedings; [3]

4. The Older Americans Act, which requires state planning agencies to use outreach workers who are fluent in the languages of older LEP persons, where there is a substantial number of such persons in a planning *area:*[4]

5. The Substance Abuse and Mental Health Administration Reorganization Act, which requires services provided with funds under the statute to be bilingual if appropriate:[5]

6. The Disadvantaged Minority Health Improvement Act, which requires the Office of Minority Health (OMH) to enter into contracts to increase the access of LEP persons to health care by developing programs to provide bilingual or interpreter services:[6]

7. The Equal Educational Opportunities Act of 1974, which requires educational agencies to take appropriate action to accommodate the language differences that impede equal participation by students in instructional programs;[7] and

8. Regulations issued by the Health Care Financing Administration (HCFA)which require that evaluations for the mentally ill and mentally retarded be adapted to the cultural background, language, ethnic origin and means of communication of the person being evaluated.8

State Laws and *Regulations*

Many states have recognized the seriousness of the language access challenge and have enacted laws that require providers to offer language assistance to LEP persons in many service settings.[9] States that require language assistance include:

1. California, which provides that intermediate care facilities must use interpreters and other methods to ensure adequate communication between staff and patients: [10]

2. New Jersey, which provides that drug and alcohol treatment facilities must provide interpreter services if their patient population is non-English speaking;[11]

3. Pennsylvania, which provides that a patient who does not speak English should have access, where possible, *to* an interpreter;[12] and

4. Massachusetts, which in April 2000, enacted legislation that requires every acute care hospital to provide competent interpreter services to LEP patients in connection with all emergency room services.[13]

Medical *Accreditation* Organizations

1. The Joint Committee on Accreditation of Healthcare Organizations (JCAHO), which accredits hospitals and other health care institutions, requires language assistance in a number of situations. For example, its accreditation manual for hospitals provides that written notice of patients' rights must be appropriate to the patient's age, understanding and language.[14]

2. The National Committee for Quality Assurance (NCQA),which provides accreditation for managed care organizations, also requires language assistance in a variety of settings. As part of its evaluation process, the NCQA assesses managed care member materials to determine whether they are available in languages, other than English, spoken by major population groups.

October 26, 2001.

Memorandum **for** Heads of Departments and Agencies **General** Counsels and Civil **Rights** Directors

From: Ralph F. Boyd, Jr., Assistant Attorney General, Civil Rights Division

Subject: Executive Order 13166 (Improving Access to Services for Persons with Limited English Proficiency)

Federal agencies have recently raised several questions regarding the requirements of Executive Order 13166. This Memorandum responds to those questions. As discussed below, in view of the clarifications provided in this Memorandum, agencies that have issued Limited English Proficiency ("LEP") guidance *for* their recipients pursuant to Executive Order 113166 and Title VI of the Civil Rights Act should, after notifying the Department of Justice ("DOJ"),publish a notice asking for public comment on the guidance documents they have issued. Based on the public comment it receives and this Memorandum, an agency may need to clarify or modify its existing guidance to the Department of Justice. Following approval by the Department of Justice and before finalizing its guidance, each agency should obtain public comment on their proposed guidance documents. With regard to plans for federally conducted programs and activities, agencies should review their plans in light of the clarifications provided below.

Background of Executive Order 13166

The legal basis for Executive Order 13166 is explained in policy guidance issued by the Department of Justice entitled "Enforcement of Title VI of the Civil Rights Act of 1964— National Origin Discrimination Against Persons With Limited English Proficiency." 65 **F.R.** 50123 (August 16, 2000). This "DOJ LEP Guidance" was referenced in and issued concurrently with the Executive Order.

As the DOJ LEP Guidance details, Title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, or national origin in any program or activity receiving federal financial assistance. Department of Justice regulations enacted to effectuate this prohibition bar recipients of federal financial assistance from "utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination" because of their race, color, or national origin. These regulations thus prohibit unjustified disparate impact on the basis of national **origin.**

As applied, the regulations have been interpreted to require foreign language assistance in certain circumstances. For instance, where a San Francisco school district had a large number of non-English speaking students of Chinese origin, it was required to take reasonable steps to provide them with a meaningful opportunity *to* participate in federally funded educational

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[1] 42 **U.S.C.** Section 1973 b(f)(1).

[2] 7 **U.S.C** Section 2020(e)(1) and (2)(A)

[3] 28 U.S.C. Section 1827(d)(1)(a).

[4] 42 U.S.C. Section 3027(a)(20)(A).

[5] 42 U.S.C. Section 290aa(d)(14).

[6] 42 U.S.C. Section 300u-6(b)(7).

[7] 20 U.S.C. Section 1703(f).

[8] 42 C.F.R. Section 483.128(b).

[9] At least twenty six 126) states and the District of Columbia have enacted legislation requiring language assistance, such **as** interpreters **and/or** translated forms and other written materials, for LEP persons.

[10] 22 California Code of Regulations, Section 73501. California has a wide array of other laws and regulations that require language assistance, including those that require: **(a)** Intermediate nursing facilities to use interpreters and other methods to ensure adequate communications with patients, (b) adult day care centers to employ ethnic and linguistic staff **as** indicated by participant characteristics. (c) certified interpreters for non-English speaking persons at administrative hearings, and (d) health licensing agencies to translate patients rights information into every language spoken by 1% or more of ***the*** nursing home population.

[11] New Jersey Administrative Code Section 42A–6.7.

[12] 28 Pennsylvania Administrative Code Section 103.22(b)(14).

[13] M.G.L.A. 111,Section 25].

[14] JCAHO, 1997 Accreditation Manual for Hospitals, Section R1.1.4.

programs. *Lau* v. Nichols, 414 U.S. 563 (1974).

The Supreme Court most recently addressed the scope of the Title VI disparate impact regulations in Alexander v. Sandoval, 121 S. Ct. 1511 (2001). There, the Court held that there is no private right of action to enforce these regulations. It ruled that, even if the Alabama Department of Public Safety's policy of administering driver's license examinations only in English violates the Title VI regulations, a private party could not bring a case to enjoin Alabama's policy. some have interpreted Sandoval as impliedly striking down Title VI's disparate impact regulations and thus that part of Executive Order 13166 that applies to federally assisted programs and activities.[2]

The Department of Justice disagrees. Sandoval holds principally that there is no private right of action to enforce the Title VI disparate impact regulations. It did not address the validity of those regulations or Executive Order **13166.** Because the legal basis for Executive Order 13166 is the Title VI disparate impact regulations and because Sandoval did not invalidate those regulations, it is the position of the Department of Justice that the Executive Order remains in force.

Requirements of Executive **Order 13166**

Federally Assisted Programs and Activities. The DOJ LEP Guidance explains that, with respect to federally assisted programs and activities, Executive Order 13166 "does not create new obligations, but rather, clarifies existing Title VI responsibilities." Its purpose is to clarify for federal-funds recipients the steps those recipients can take to avoid administering programs in a way that results in discrimination on the basis of national origin in violation of the Title VI disparate impact regulations. To this end, the Order requires each Federal Agency providing federal financial assistance to explain to recipients of federal funds their obligations under the Title VI disparate impact regulations.

In developing their own LEP guidance for recipients of federal funds, an agency should balsnce the factors set forth in the DOJ LEP Guidance. These factors include, but are not limited to (i) the number or proportion of LEP individuals, (ii) the frequency of contact with the program, (iii) the nature and importance of the program, and (iv) the resources available.

As the DOJ LEP Guidance explains, "a factor in determining the reasonableness of a recipient's efforts is the number or proportion of people who will be excluded from the benefits or services absent efforts to remove language barriers." Similarly, the frequency of contact must be considered. Where the frequency and number of contacts is so small as to preclude any significant national origin based disparate impact, agencies may conclude that the Title VI disparate impact regulations impose no substantial LEP obligations on recipients.

The nature and importance of the program is another factor. Where the denial or delay of access may have life or death implications, LEP services are of much greater importance than where denial of access results in mere inconvenience.

Resources available and costs must likewise be weighed. A small recipient with limit-ed resources may not have to take the same steps as a larger recipient. See DOJ LEP Guidance at 50125. Costs, too. must be factored into this balancing test. "Reasonable steps" may cease to be reasonable where the costs imposed substantially exceed the benefits in light of the factors outlined in the DOJ LEP Guidance. The DOJ LEP Guidance explains that a small recipient may not have to take substantial steps "where contact is infrequent, where the total costs of providing language services is relatively high and where the program is not crucial to an individual's day-to-day existence." By contrast, where number and frequency of contact is high, where the total costs for LEP services are reasonable, and where the lack of access may have life and death implicates, the availability of prompt LEP services may be critical. In these latter cases, claims based on lack of resources will need to be well substantiated.

Finally, consideration of resources available naturally implicates the "mix" of LEP services required. While on-the-premise translators may be needed in certain circumstances, written translation, access to centralized translation language lines or other means may be appropriate in the majority of cases. The correct balance should be based on what is both necessary to eliminate unjustified disparate impact prohibited by the Title VI regulations and reasonable in light of the factors outlined in the DOJ LEP Guidance.

Federally Conducted Programs and Activities. Executive Order 13166 **also** applies to federally conducted programs and activities. With respect to these, the Order requires each Federal Agency to prepare a plan to improve access to federally conducted programs and activities by eligible LEP persons. These plans, too, must be consistent with the DOJ LEP Guidance. Federal agencies should apply the same standards to themselves as they apply to their recipients.

Procedural Considerations

Administrative Procedure Act: Agency action taken pursuant to Executive Order 13166 and the DOJ LEP Guidance may be subject to the Administrative Procedure Act's ("APA") rulemaking requirements. 5 U.S.C. §553. Although interpretive rules, general statements of policy, and rules of agency organization and procedure are not subject to section 553, courts have ruled that any final agency action that carries the force and effect of law must comply with section 553's notice and comments requirements. See *Paralyzed Veterans* of America *v. D.* C. Arena, 117 F.3d 579, 588 (D.C. Cir. 1997). Agencies, therefore, should consider whether the action they have taken or that they propose to take to implement Executive Order 13166 and Title VI of the Civil Rights Act is subject to **the** APA's requirements. If it is, they must comply with these statutory obligations. Agencies must bear in mind, however, that Executive Order 13166 "does not create new obligations, but rather, clarifies existing Title VI responsibilities." Accordingly, agency action taken pursuant to Executive Order 13166 must not impose new obligations on recipients of federal funds, but should instead help recipients to understand their existing obligations.

Executive Order 12866: Agency action taken pursuant to Executive Order 13166 and the DOJ LEP Guidance may also be subject to requirements set **forth** in Executive Order 12866 (Regulatory Review and Planning, Sept. 30, 1993). That Order directs agencies to submit to the Office of Management and Budget for review any "significant regulatory actions" the agency wishes to take. See § 6(a). Agencies, therefore, should consider whether the action they have taken or that they propose to take to implement Executive Order **13166** and Title VI of the Civil Rights Act is subject to Executive Order 12866's requirements. If it is, they should ensure that the action or proposed action complies with Executive Order 12866's obligations. With regard to federally conducted programs and activities, agencies should review their plans for their federally conducted programs in light of the clarifications below and make any necessary modifications.

Further Agency Action

Existing LEP Guidance and Plans *for* Federally Conducted Programs and Activities: Agencies that have already published LEP guidance pursuant to Executive Order 13166 or Title VI of the Civil Rights Act should obtain public comment on the guidance documents they have issued. Agencies should then review their existing guidance documents in view of public comment and for consistency with the clarifications provided in **this** Memorandum. The Justice Department's Civil Rights Division, Coordination and Review Section ((202) 307–2222), is available to assist agencies in making this determination. Should this review lead an agency to conclude that it is appropriate to clarify or modify aspects of its LEP guidance documents. it should notify the Department of Justice of that conclusion within 60 days from the date of this Memorandum. Any agency effort to clarify or modify existing LEP guidance should be completed within 120 days from the date of this Memorandum. Agencies likewise should review plans for federally conducted programs and activities in light of the above clarification.

New *LEP* Guidance and Plans for Federally Conducted Programs and Activities: Agencies that have not yet published LEP guidance pursuant to Executive Order 13166 and Title VI of the Civil Rights Act should submit to

[1] "It seems obvious that the Chinese-speaking minority receive fewer benefits than the English-speaking majority from respondents' school system which denies them a meaningful opportunity to participate in the education program—all earmarks of the discrimination banned by the regulations." 414 U.S. at 568.

[2] *See Sandoval*, 121 S. Ct. at 1519 n.6 ("[W]e assume for purposes of this decision that § 602 confers **the** authority to promulgate disparate-impact regulations; * * * **We** cannot help observing, however, how **strange** it is to say that disparate-impact regulations are 'inspired by, at the service of, and inseparably intertwined with' § 601 * * * when § 601 permits the very behavior that the regulations forbid."].

the Department of justice, within 60 days from the date of this Memorandum, agency-specific recipient guidance that is consistent with Executive Order 13166 and the DOJ LEP Guidance, including the clarifications set forth in this Memorandum. In preparing their guidance, agencies should ensure that the action they propose to take is consistent with the requirements of the Administrative Procedure Act and Executive Order 12866. The Justice Department's Civil Rights Division, Coordination and Review Section, is available to assist agencies in preparing agency-specific guidance. Following approval by the Department of Justice and before finalizing its guidance, each agency should obtain public comment on its proposed guidance documents. Final agency-specific LEP guidance should be published within 120 days from the date of this memorandum. Agencies likewise should submit to the Department of Justice plans for federally conducted programs and activities. The Department of Justice is the central repository for these agency plans.

* * * * *

Federally assisted programs and activities may not be administered in a way that violates the Title VI regulations. Each Federal Agency is responsible for ensuring that its agency-specific guidance outlines recipients' obligations under the Title VI regulations and the steps recipients can take to avoid violating these obligations. While Executive Order 13166 requires only that Federal Agencies take steps to eliminate recipient discrimination based on national origin prohibited by Title VI, each Federal Agency is encouraged to explore whether, as a matter of policy, additional affirmative outreach to LEP individuals is appropriate. Federal Agencies likewise must eliminate national origin discrimination in their own federally conducted programs and activities. The Department of Justice is available to help agencies in reviewing and preparing agency-specific LEP guidance and federally conducted plans.

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Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration [HCFA)),Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; **(3)** ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Type *of* Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Disproportionate Share Hospital Payments — Institutions for Mental Disease; Form *No.* HCFA–R–0266 (OMB# 0938–0746); Use: This PRA package announces the Federal share of disproportionate share hospital (DSH) allotments for Federal fiscal years (FFYs) 1998 through 2002. It also describes the methodology for calculating the Federal share DSH allotments for FFY 2003 and thereafter, and announces the FFY 1998 and FFY 1999 limitations on aggregate DSH payments States may make to institutions for mental disease (IMD) and other mental health facilities; Frequency: Annually; Affected Public: State, Local, or Tribal Government; Number of Respondents: 54; Total Annual Responses: 54; Total Annual Hours: 2,160.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown, CMS–R–266, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 9, 2002.

John P. **Burke, III,**

Reports *Clearance Officer, Security and Standards Group,* Division of *CMS Enterprise Standards.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–2786]

Agency information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services [CMS) (formerly known as the Health Care Financing Administration (HCFA)),Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden: **(3)** ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection *Request:* Extension of a currently approved collection; Title *of* Information Collection: Fire Safety Survey Report Forms and Supporting Regulations in 42 CFR 416.44, 418.100, 482.41, 483.70, 483.470; Form No.: CMS–2786 A–D, F, G, H, J, K, L, M, P and Q (OMB# 0938–0242); Use: The information from these forms will be used to make Medicare/Medicaid certification decisions. We request information in accordance with the Life Safety Code of the National Fire Protection Association. CMS then surveys all facilities based upon prior compliance history; that is, the "good" facilities will be surveyed less frequently. Either the short or long fire safety form will be utilized each time a health survey is performed, depending

JAMES E. ZINI, D.O.
PRESIDENT

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March 5,2002

Christy Schmidt, Executive Coordinator
Regulatory Reform Initiative
Office of the Assistant Secretary for Planning and Evaluation
200 Independence Ave., SW
Washington, D.C. 20201

Dear Ms. Schmidt:

Thank you for the opportunity to recommend ways to reduce burdens imposed by existing health care regulations.

The American Osteopathic Association (AOA) represents more than 48,000 osteopathic physicians nationwide with approximately 64% practicing in Family Medicine, Internal Medicine, Pediatrics, and Obstetrics and Gynecology. Osteopathic physicians represent 18% of all physicians practicing in small towns and rural areas with populations of 10,000 or less, and 22% of all physicians practicing in communities of 2,500 persons or less.

As president of the AOA, I am deeply concerned that many of the regulations inhibit the delivery of good quality care. **The regulatory burden has physicians near the breaking point.** Many physicians limit the number of Medicare patients they see because they cannot handle the increasing regulatory workload. Patients, particularly in rural areas, must travel greater distances to find physicians who accept Medicare.

We appreciate the efforts of the HHS Advisory Committee on Regulatory Reform to identify regulations that impose barriers to high quality health care services and to recommend ways to remove those barriers. We understand, however, that the Advisory Committee may plan to focus primarily on regulations that come out of the Centers for Medicare and Medicaid Services and the Food & Drug Administration. We hope that you expand your focus to cover other agencies such as the HHS Office of Civil Rights (OCR), which oversees the implementation of the privacy regulations and Limited English Proficiency guidelines, both of which have raised great concerns within the physician community.

Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164): Protecting a patient's privacy already is part of a physician's daily practice. Adding the substantial papenvork requirements, personnel and systems changes required by the new regulation (mandated by the **Health Insurance Portability and Accountability Act of 1996)** will take vital time and resources away from patient care and may not result in any significant improvement in patient confidentiality. We appreciate that OCR plans to release proposed modifications to the privacy rule in an effort to make compliance more manageable while still protecting a patient's medical records. These proposed modifications are still in the review process. The publication date is not yet known and the proposals may not fully address the concerns that now exist. For example, under **Section 164.522 – Right of an**

individual to request restriction of uses and disclosures, patients may object to labeling conditions such as diabetes or chronic depression in their medical records. Sensitive medical information has an important bearing on the type of medication or treatment prescribed. Although the final rule allows physicians to deny a patient's request for restrictions, forcing doctors and patients to negotiate over the medical records may strain the already delicate physician-patient relationship. Under **Section: 164.504: Uses and disclosures; organizational requirements (Business Associate contracts),** there is still confusion over who is a business associate and when a business associate is required to sign a contract due to the direct and indirect health care providers provisions. This section needs to be clarified. We believe the rule could be simplified by requiring a statement in the service contract that a business associate will treat information as though they were the physicians for privacy purposes. **Section 164.506: Consent for uses or disclosures to carry out treatment, payment, or health care operations** will interfere with the routine administration of health care, delay patient care, and create confusion among patients and physicians. Obtaining prior consent should be discretionary, not mandatory for covered entities. ***Recommendation:*** *HHS needs to reduce the administrative costs as much as possible and eliminate the requirement that physicians be the enforcer of the regulations. The regulations must not intrude on the physician-patient relationship,*

Limited English Proficiency: The financial implications of having to comply with OCR's policy guidance standards **(Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency, 65 FR 52762)** could be devastating. For example, fees for a professional interpreter can run $40/hour or more with a two-hour minimum. If the interpreter fees end up costing more than the amount a physician actually is paid for a service, how is the physician expected to cover his/her costs? Concerns regarding costs and resources apply to the translation of written materials also, particularly when more than one foreign language is used. ***Recommendation:*** *The Office of Civil Rights should implement an immediate moratorium on the LEP regulation until the Administration can discuss the issue with all impacted parties to determine'the best solution.*

Other troublesome Centers for Medicare and Medicaid Services' regulations include:

Emergency Medical Treatment and Active Labor Act: We support the original congressional intent of EMTALA. However, CMS's extension of EMTALA **(Example: Medicare Program Prospective Payment System for Hospital Outpatient Services Final Rule, 42 CFR Sec. 489.24)** goes beyond the original intent of the law. Hospitals and physicians face overcrowded emergency departments, a lack of access to critical specialty emergency care, and significant compliance costs associated with EMTALA that provide little, if any, added value to patient care.

For example, a patient may go to an emergency department seeking a pregnancy test. The patient is given the option of being seen in the emergency department or going to the walk-in OB-GYN clinic within the hospital grounds. Under EMTALA rules, the emergency physicians are required to log the patient in, escort the patient to the clinic and then log the patient out. In many cases, it is just easier to see the patient, do the test and discharge the patient with an appointment. However, this solution only continues to reinforce the view that emergency department physicians are the primary care providers. The emergency department physicians end up giving free primary care services to non-urgent care patients. ***Recommendation:*** *CMS needs to implement more narrow interpretations that do not* ***exceed*** *the intent of the* ***law.*** *In addition, regional carriers should have some degree of uniformity in the interpretation and enforcement of EMTALA. As it*

stands now, there are varying interpretations of the EMTALA requirements among the regional carriers, making it all the more difficult to comply.

Carrier and Agency Accountability: In the mid 1990s, three osteopathic physicians in Oklahoma established rural health clinics in the towns of Morrison, Yale, Pawnee and Fairfax with the guidance of CMS's regional office in Dallas. The regional office guided the doctors in establishing the federally designated rural health clinics and approved them. Three years later, CMS headquarters in Baltimore informed the doctors that they were overpaid and requested a repayment of $980,000, despite the fact that the local carrier confiimed in writing that the physicians followed the guidelines correctly. In an effort to recover the money, all Part **A** Medicare payments were stopped. It was ultimately determined that the regional office provided the wrong information to the physicians regarding the establishment of the clinics. The rural health clinics were forced into bankruptcy. The error caused by the Federal government's regional office had devastating effects -- the doctors and patients paid the price. ***Recommendation:*** *We concur with MedPAC's reconmendation in its* ***December 2001 report: Reducing Medicare Complexity and Regulatory Burden*** *that the Medicare program should provide timely, binding written guidance to plans and providers. Plans and providers that rely on such guidance should not be subject to civil or criminal penalties or be required to refund related payments if that guidance is later found to be in error. In addition, contractors and the federal agencies must be held accountable for the errors they make. They should not be immune from punitive measures. Local carrier advisory committees (CACs) should continue in each state to assure that local medical review policy reflects the consensus of the local physician community, however payment policy and patient information should be consistent across the country. CMS should establish the highest possible standards to determine which Organizations are most qualified to become contractors in the program. Formal physician/provider feedback should be solicited regarding the establishment of performance criteria for contractors and whether the contractors' actions have actually met those standards.*

Medical Residents and Physician Supervision: Too much papeiwork and not enough time to teach is a serious problem facing doctors at teaching hospitals. CMS requires physicians at teaching facilities to supervise key portions of procedures and services provided by the residents, interns and fellows. In addition, for daily care and initial patient visits, CMS requires complete documentation of the entire visit by the attending physicians for different levels of services billed. This is redundant because the trainees are documenting the patient visit, assessment and plan. The role of the attending physician should be of higher order management and teaching. Doctors are less inclined to teach due to the burdens of documentation. Residents are concerned that faculty have less time for overall teaching, resulting in less time for mentoring; physicians see no reward for teaching especially with the PATH audits; and as ancillary services have decreased in selective programs, first year GME trainees are spending more time performing administrative tasks and less time with patients. ***Recommendation:*** *Promote the highest standard of physician education; promote and recommend increased, stable GME funding and compensate physicians for teaching; strengthen peer review; readdress CMS documentation guidelines; and keep residents involved in the process of guidelines development.*

Evaluation and Management Documentation Guidelines: Physicians need to maintain complete, accurate medical records to help ensure good quality of care, which is the primary purpose of documentation. Until documentation guidelines are revised, physicians must use either the 1995 guidelines, which are not complete -- or 1997 guidelines, which are very cumbersome. ***Recommendation:*** *CMS should suspend all pre- and post-payment audits of evaluation and management services until the guidelines are finalized. Physicians are in the dark in terms of how*

their records will be judged under the current system. Extensive education is necessary for both the physician community and the Medicare carriers so that no confusion exists.

Claims Resubmission: Physicians are burdened when CMS or carrier edits deny claims in error, because once that error is corrected, it often becomes the responsibility of the physician office to resubmit the claim for payment. ***Recommendation:*** *The physician should not be burdened to resubmit the claim that was correct from the beginning. It is the responsibility of the carrier and CMS to correct its error and pi-ovide proper payment in an expedient manner that is not time-consuming for the physician and staff.*

Coverage of follow-up visits for cancer patients: Physicians are concerned about carrier denials for services, such as cancer monitoring, that physicians believe to be medically necessary. Some of these visits are classified as "screening" services by some camers and therefore denied. ***Recommendation:*** *Cancer patients require monitoring to track the progression, remission and reoccurrence of the disease. Cancer monitoring is vitally important for the patient and is medically necessary. Payment should not be denied.*

Coverage of Pre-Op Evaluations: Physicians are concerned about carrier denials for services, such as pre-operative evaluations, that physicians believe to be medically necessary. They have stated that some testing and examinations performed as part of a "preoperative work-up" are being classified as "screening" services by some carriers and therefore denied. ***Recommendation:*** *Denials for pre-surgical evaluations are common, especially if they are performed on the same day as surgery, and it requires a significant amount of paperwork to receive payment. Pre-op evaluations should be reimbursed.*

Eligibility Determinations: Some physicians have stated that it is difficult to determine whether a beneficiary is enrolled in Medicare Managed Care or Medicare Fee for Service. This is important throughout the day as tests and consultations are scheduled. Patients often are sent home because of a lack of referrals. Referrals are too paper-intensive and neither the patient nor referring doctors manage them well. To resolve this, CMS released instructions on October 12, 2001, **Transmittal AB-01-137,** authorizing contractors to communicate eligibility information to physicians and providers by telephone without violating patient confidentiality. However, problems still exist. ***Recommendation:*** *Medicare needs to educate beneficiaries regarding the requirements under Managed Care.*

Seclusion and Restraints medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights; Interim Final Rule: 42 CFR 482.13): Some physicians disagree with the requirement that a physician or licensed independent practitioner must see/examine a patient within 1 hour of giving an order for the use of seclusion and/or restraints. This requirement is not always feasible, is burdensome, and may fail to promote higher quality of care. ***Recommendation:*** *Restraints are necessary when a patient is dangerous to staff or to him/herself. The one-hour requirement is not workable. This provision requires flexibility particularly in rural areas where staffing in hospitals is limited.*

Clinical Lab Improvement Act (42 CFR 493): CLIA 88 requirements are burdensome and costly. For example, physicians are discouraged from doing simple tests and are forced to send patients to labs located elsewhere. Many times this results in patients failing to have the lab tests done as it requires them to physically go to another location and take additional time off work. **A** lab within the physician's office allows for immediate lab results and immediate treatment without

inconveniencing the patient. ***Recommendation:*** *CMS should review the laboratory tests to determine if any can be moved to a more appropriate and administratively simpler test category.*

Extrapolation: When carriers identify an alleged physician billing error, they can "extrapolate" the single identified error to the physician's other claims, resulting in an allegation that the physician has been overpaid by tens of thousands of dollars. This would be like the IRS identifying an error on your most recent tax return and making the assumption that you made that error on every tax return you had ever filed and then requesting back taxes on each and every return. ***Recommendation:*** *End this unfair practice especially for first-time audits.*

Prohibit Payment Demands Until Fair Determination: CMS requires that alleged "overpayments" to physicians be repaid within 60 days, even if physicians appeal CMS's allegations. Congress repealed a similar unfair practice by the IRS in the IRS Restructuring and Reform Act of 1998. Many alleged overpayment amounts are substantially reduced on appeal. ***Recommendation:*** *If a physician appeals the allegation, payment by the physician should not be demanded until after the appeal is heard and the arbitrator actually deems that the physician owes CMS money.*

Provide Meaningful Options for Appeals: When assessed a Medicare overpayment, the only way physicians can appeal is to subject their practices to another audit, in which CMS uses a "statistically valid random sample." Statistical sample audits can shut down a physician's practice for days, preventing patient treatment. Physicians are forced to settle with CMS rather than be subjected to unfair scrutiny. This would be like the IRS saying that the only way to appeal an audit of your 1998 return is for it to audit 10 more returns. ***Recommendation:*** *Physicians have a right to a fair appeal on an individual audit without being subject to additional audits, which intrude unnecessarily on the physicians' practices.*

Protect Health Professions from Unfunded Federal Mandates: Physicians are expected to implement costly federal mandates without any compensation by the government. ***Recommendation***: *Physicians should be protected from future unfunded federal mandates by requiring that Medicare payment rates better reflect the mandates' costs imposed on physicians and other health care providers.*

Thank you again for this opportunity. We look forward to working with HHS on this and other issues of importance to members of the osteopathic medical profession and the patients we serve. We appreciate your consideration of our concerns.

Sincerely,

James E. Zini D.O

James E. Zini, D.O.
AOA President

cc: President-Elect, AOA
Members, Board of Trustees, AOA
Chairman, Department of Government Affairs, AOA
Chairman and Members, Council on Federal Health Programs, AOA
Executive Director, AOA

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August 17,2001

Murray N. Ross, Ph.D
Executive Director
Medicare Payment Advisory Commission
1730 K Street, NW, Suite 800
Washington, D.C. 20006

Dear Dr. Ross:

The American Osteopathic Association commends Congress for directing MedPAC to evaluate the burden placed on providers through federal regulations. We look forward to MedPAC's recommendations to reduce the regulatory complexity of the Medicare program.

The AOA welcomes MedPAC's exploration of how changes in law and regulation may improve the program, including improvement of the rules regarding quality of care requirements, billing, compliance, fraud and abuse, and beneficiary protections. The AOA offers its views on questions released by MedPAC:

Do current regulations help Medicare fulfill its responsibility to be a prudent purchaser of health care services and to promote access to quality care for its beneficiaries?

We believe the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration, make a good faith effort to develop appropriate regulations to ensure quality health care. **However, the regulations issued in recent years have done more to increase administrative requirements and little to improve health care services.**

Under complex federal regulations, physicians must comply with numerous mandates to complete claim forms, advance beneficiary notices, certify medical necessity, file enrollment forms and comply with code documentation guidelines. The quality of health care suffers due to excessive regulations that divert time **and** resources away from patient services to fulfill administrative requirements.

The regulatory burden has physicians at the near breaking point. Physicians limit the number of Medicare patients they see because they cannot handle the increasing regulatory workload. Patients, particularly in rural areas, must travel greater distances to find physicians who accept Medicare.

True regulatory reform must take into account that the physician and hospital communities comply with regulatory requirements on the local, state and federal level. When creating or revising regulations, CMS must examine the additional regulatory requirements to ensure that Medicare regulations are compatible. Under the Health Insurance Portability and Accountability Act (HIPAA), a state statute pre-empts federal requirements if the state statute is stronger. Physicians find it extremely difficult to determine what is pre-empted. Without compatibility, providers face the daunting task of complying with regulations that oftentimes are inconsistent, contradictory and confusing.

How has the regulatory complexity of the Medicare program changed in recent years? How have these changes affected the delivery of care?

Congress passes laws to resolve problems and to improve programs, but oftentimes, more problems arise as a result of the regulatory implementation of those laws. Highlighted below are just a few examples of the many problems that now exist.

Congress passed numerous laws in the past decade affecting the Medicare system. The regulations that implement these laws are now talung effect, requiring the health care community to engage in a massive overhaul of the health care system.

For example, regulations stemming from the law limiting certain physician referrals, also known as the **Stark law,** had significant implementation problems and resulted in having to amend the original law. The laws were enacted in 1993, with an effective date of January 1995. But, the proposed rule was not issued until 1998, and the final rule was issued in January 2001.

The essence of the Stark prohibition is that a physician cannot refer a Medicare patient to an entity for a designated health service if there is a financial relationship between the referring physician or an immediate family member and the DHS provider, unless an exception is applicable.

Between 1993 and 2001, many joint ventures were in limbo awaiting regulations. Once the regulations were issued, many ventures had to be rearranged and reconstituted. For example, under the rules in 1995, solo practice physicians individually renting space in a medical arts building could not jointly operate a lab for the convenience of their patients and patient care. Patients, particularly in rural areas, had to travel many miles for lab tests. However, under the 2001 regulation, this situation is allowed.

Before the correction, many physicians chose to ignore the law and risked being in violation so that patients could have the convenience of lab tests. The 2001 Stark rule solved some problems but created additional difficulties and unintended consequences, which continue to hamper patient care.

Another example involves the Emergency Medical Treatment and Active Labor Act (EMTALA). Although it was originally enacted in 1986, its requirements have expanded in recent years. In 1994, CMS issued regulations for EMTALA and in 1998 the agency released interpretive guidelines.

We support the original congressional intent of EMTALA. The law provides that all patients who go to a hospital emergency department seeking emergency medical services should receive a medical screening examination and stabilizing treatment. The ability to pay must not be a factor in determining whether treatment will be provided.

The extension of EMTALA to cover ambulances, free standing clinics and off campus facilities goes beyond the original intent of the law. EMTALA requirements strain the ability of the medical profession to provide the quality of care that patients deserve. Hospitals and physicians face overcrowded emergency departments, a lack of access to critical specialty emergency care, and **the significant compliance costs associated with EMTALA that provide little, if any, added value to patient care.**

The CMS should not penalize or prevent hospitals from refemng patients to continuity care clinics on the hospital grounds. EMTALA discourages emergency departments from referring non-urgent care patients back to their primary care provider. Under the current situation, the EMTALA rules reinforce the view that emergency department physicians are primary care providers. The emergency department physicians end up giving free primary care services to non-urgent care patients. In addition, physician

liability under EMTALA has made it difficult for hospitals to find physicians willing to be on call. As a result, we may be compromising the quality of health care delivered.

In 1996, Congress passed the Health Insurance Portability and Accountability Act. Not all of the regulations stemming fiom this law have been finalized, but the ones that have been finalized in recent months are causing severe financial and administrative difficulties.

Health care providers must comply with the standards for electronic transactions, which implement some of HIPAA's administrative simplification provisions, by October 2002. However, recent studies found that the health care community and state agencies will not be ready by the deadline. In addition, since CMS must still finalize more regulations under HIPAA, this may require more administrative and technical changes, adding to the financial strain.

A coalition of physician, hospital and insurance associations are calling on Congress to pass an extension to the implementation period. Otherwise hospitals, doctors, and health plans will be forced to continually revisit and rework systems, policies and procedures each time a new rule is released, costing millions of dollars.

In addition, the privacy regulation under HIPAA caused great confusion, prompting HHS to release clarifications and plan to issue new proposed rules to modify provisions concerning phoned-in prescriptions, referral appointments, allowable communications and minimum necessary scope.

The AOA supports protecting the privacy of patient medical records. Physicians are bound ethically to do so. However, the government has unfettered access to medical records without the need of a subpoena or due process.

Again, the health care community is forced to expend already limited resources to implement federal requirements that will do more to strain the health care system than improve it. HIPAA creates another whole new bureaucracy.

Another example is the length of time it takes for a federal agency to address an issue. It took ten years for the federal government to approve new language for the Advance Beneficiary Notice so that it no longer uses the phrase "medically unnecessary."

Have increased fraud and abuse investigative actions affected service to Medicare beneficiaries? How can Medicare deter improper billing in a non-punitive environment?

The Medicare system has many fundamental problems, which are out of the physician community's control. Those problems are rooted in the multitude of regulations and policies that physicians must follow and the lack of effective support fiom CMS and their local camers.

Physicians are forced to work in a climate of distrust where they fear a simple error could turn into a fraud investigation. In an effort to protect themselves, many physicians down code or fail to bill for services. They do so to avoid scrutiny for billing for more complex services, despite the fact that the higher service was warranted.

Most improper billing is a result of honest errors and confusion over the claims submission requirements – not fraud. Education and clear communication are essential keys to detemng improper billing. **A** major source of the problems with claims submission is a result of inaccurate information fiom camers, intermediaries, as well as CMS.

CMS appears to encourage an environment of distrust between the providers and the beneficiaries with such things as the Senior Medicare Patrol Project, Medicare press releases, and carrier beneficiary news releases. Instead of encouraging beneficiaries to review any discrepancies in their Medicare billing with providers, beneficiaries are encouraged to contact the Medicare hotline. Beneficiaries should be encouraged to contact their doctor or provider's office first to resolve billing problems. If unsuccessful, then they may contact the hotline for further assistance.

We respect CMS's new efforts to enhance provider education activities and open new lines of communication with the provider community. CMS centralized its educational efforts in its Division of Provider Education and Training. The agency also provides contractors with in-person instruction and standardized training manuals for them to use in educating physicians and other providers.

CMS works with the physician and provider community to improve communications and responsiveness to their concerns. CMS plans to expand its Medicare provider education web site; provide free computer and web-based training courses; and create a more useful agency web site. We commend the efforts to have CMS regional meetings with representatives of local medical societies.

While we respect CMS's recent initiatives, it is questionable that they will be enough to alleviate the unnecessary burdens physicians now face. MedPAC's report to Congress is just as important. An ongoing concerted investigation is essential because regulatory burden is a huge problem.

The AOA supports the Medicare Education and Regulatory Fairness Act (MERFA) which better targets current Medicare education dollars to provide needed outreach and education to physicians and health care providers -- especially those in rural communities -- on the complexities of Medicare billing. We are disappointed, however, that CMS opposes certain elements of MERFA that it believes would weaken enforcement measures.

What is the frequency and nature of your interactions with administrative personnel from the Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), its fiscal intermediaries and carriers as well as other Medicare contractors?

The AOA is in regular contact with the Centers for Medicare and Medicaid Services, providing comments and recommendations on its plans and proposals for the Medicare system. We are encouraged by the recent efforts of HHS and CMS to alleviate the regulatory burden and to improve the lines of communication, i.e. monthly teleconference calls, with the physician community. We believe HHS and CMS are taking the steps in the right direction to address the problems that have persisted for many years.

A significant problem lies at the contractor level. The General Accounting Office (GAO) recently reviewed contractor bulletins from 10 carriers. The GAO found that the bulletins contained lengthy discussions with overly technical and legalistic language that providers may find difficult to understand. The bulletins also omitted important infomiation about mandatory billing procedures.

The GAO found that in 85% of its phone calls, the answers were incomplete or inaccurate. In addition, carrier Internet sites rarely met all CMS requirements and lacked user-friendly features such as site maps and search functions. We frequently hear of such Complaints from our membership. Our members also find that carriers at times are unwilling to put their communications with physician practices in writing.

What aspects of Medicare do you find most/least burdensome?

Over the past seven years, CMS tned to develop Evaluation and Management documentation guidelines. The AOA commends the agency for working with the physician community and committing much time and effort into the development of the guidelines, which has proven to be a difficult task. Until new guidelines are established, physicians work with the 1995 and 1997 guidelines. This process is confusing and cumbersome.

Documentation is necessary for medical purposes, however, it has become a reimbursement tool for the Medicare carriers as well as a legal tool. Without an appropnate set of guidelines, the current system does little to accomplish any purpose, other than to require more time to paperwork and allow less time for actual patient care.

We requested that the CMS delay the timetable currently in effect with Aspen Systems. CMS stopped work on the guidelines until a task force can address the issues concerning the physician community. The AOA also believes CMS should withhold all audits of E&M service claims until the documentation guidelines are final.

What specific steps would you recommend to decrease regulatory complexity and burden in Medicare? How could those steps be implemented?

- The AOA supports federal legislation that would protect health care professionals from future, unfunded federal mandates by requiring that Medicare payment rates better reflect the costs of mandates imposed on physicians and other health providers.
- Carriers and fiscal intermediaries need to be trained and educated to give appropriate claims processing guidance to physician practices. Physicians should not be punished when provided inaccurate information from their contractors, as is often the case.
- Congress and CMS must take into account regulatory requirements at the state and local level to develop federal rules that are compatible.
- CMS should enhance the role of the Carrier Advisory Committees (CAC) by increasing communication and education programs through the CAC system.
- Documentation should be limited to the data necessary for appropriate billing and monitoring quality of care.

Thank you for this opportunity to provide our views. If you have further questions, please contact Carol Monaco, AOA's Assistant Director for Regulatory Affairs in our Washington Office at 202-4 14-0145.

Sincerely,

James E. Zini DO

James E. Zini, DO, AOA President

cc: President-Elect, AOA
Members, Board of Trustees, AOA
Chairman, Department of Government Affairs, AOA
Chairman and Members, Council on Federal Health Programs, AOA
Executive Director, AOA

DECEMBER 2001

REPORT TO THE CONGRESS

Reducing Medicare Complexity and Regulatory Burden

MEDPAC Medicare Payment Advisory Commission

DECEMBER 2001

REPORT TO THE CONGRESS

Reducing Medicare Complexity and Regulatory Burden

MEDPAC Medicare Payment Advisory Commission

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Executive summary

Executive summary

Many providers claim that the Medicare program is over-regulated and burdensome. Medicare started in 1966 without any regulations because there was not enough time between the passage of the act in 1965 and its implementation to write and approve them. Instead, the program used only conditions of participation for providers. Now, by one widely used estimate, over 125,000 pages of regulations—more than the Internal Revenue Service regulations for the entire tax system—control the program.[1] Providers can point out that the first section in the Social Security Act governing Medicare is a prohibition against federal interference in the practice of medicine or the manner in which it is provided, yet the program now directs how notes should be documented in a patient's medical record.

However, in addition to paying providers, the program also must protect beneficiaries and ensure that over $200 billion is spent appropriately each year. Given this tension, is Medicare over-regulated? Is the program too complex? Must complexity lead to burden on providers and beneficiaries? Does the current situation impose an unfair or unreasonable burden on providers and possibly beneficiaries? To what extent can the program be simplified and the burden reduced?

In the Balanced Budget Refinement Act of 1999, the Congress required that MedPAC study these questions. In this report, we do not attempt to catalog all the regulations in the Medicare program or the burdens and costs they impose on providers. Rather, we strive to understand some of the sources of complexity in the program and determine whether Medicare can be simplified. By getting to the source of complexity, we might be able to trim not only regulations that might be particularly nettlesome today, but also eliminate entire branches of complication and all the regulations associated with them. This larger-scale pruning of regulations can be thought of as a long-term strategy that can be pursued along with the targeted efforts already under way in the Centers for Medicare & Medicaid Services (CMS) and the Congress.

In Chapter 1, we describe the complexity of the Medicare program and investigate the sources of that complexity such as the program's size, scope and original design.

In Chapter 2, we analyze what can and cannot be simplified in the program and make seven recommendations which are outlined below.

Recommendation 1: CMS should move to a standard nationwide system of claims processing and eliminate local descriptions of policy and regulation. The Congress should allow CMS to contract as necessary to implement a standard system efficiently.

The original legislation for Medicare envisioned a very different world than now exists. It was designed for a program with local administrators paying locally determined rates for health care services. Today, the program uses nationally determined prospective payment systems but still retains multiple contractors and local policies for administration and claims payment; this adds unnecessary complexity and confusion to the program.

[1] Estimates of the number of pages of regulations or Medicare vary widely. The widely quoted 125,000 pages number included Medicaid as well as Medicare regulations when it was computed. CMS reportedly has suggested 30,000 pages is a more accurate estimate (Statement of Douglas L. Wood, M.D. Mayo Clinic to MedPAC, September 2001). As we show in Appendix A there are many levels of regulation and instruction and to some extent any number is suspect. In this report, we use the term "regulation" to encompass the broad range of requirements that govern the Medicare program and that providers, suppliers, and beneficiaries must follow. There is general agreement that the sheer mass of regulation is considerable by any measure.

Carrying out this recoinmendation would eliminate much of the complexity, inconsistency, and uncertainty in the current program and make possible one accepted statement of Medicare policy, consistent descriptions and understanding of regulations, and standard instructional materials. The change also would lessen the regulatory burden on providers and beneficiaries, help them get more consistent and correct answers, and set the stage for implementing Recomniendation 2.

Recommendation 2: The Medicare program should provide timely, binding written guidance to plans and providers. Plans and providers that rely on such guidance should not be subject to civil or criminal penalties or be required to refund related payments if that guidance is later found to be in error.

Providers cannot now rely on answers from Medicare to protect them against future prosecution. If some of the layers of the present system were cut out, the probability of correct, timely information being communicated would be increased. It might then be possible to assure providers who make a good faith effort to follow guidance that they will not be held liable for additional penalties or be required to refund related payments if that guidance were incorrect.

Recommendation *3:* CMS should explore ways to reduce routine administrative requirements for plans and providers that demonstrate sustained good performance.

Fear of unfounded prosecution and the formidable array of enforcement tools available to the Medicare program have created fear among providers. Well-intentioned providers are cowed from appropriate behavior or even from participating in the program because rules are written for the few "bad apples" rather than for the vast majority of honest providers. Rewarding good behavior has the advantage of encouraging compliance and simplifying administration of the program; for example, data can be collected less frequently from plans and providers that demonstrate sustained good perfomiance. Private-sector models should be investigated as CMS evaluates pursuing such a strategy in the Medicare program.

Recommendation 4: The Secretary of Health and Human Services should work with the Department of Justice to improve consistency and eliminate redundancy in enforcement roles and activities.

Another problem in enforcement is that many entities that may be poorly coordinated are involved in setting, interpreting, and enforcing rules. Because the enforcement agencies have grown with their increased activity in fraud and abuse, their roles may no longer be optimal for the current environment. Rationalizing resources to emphasize provider education and improve communication to avoid government waste can be accomplished administratively, but statutory changes would be required to transfer or consolidate which executive branch agency could levy penalties, exclude providers, and prosecute civil or criminal penalties.

Recommendation 5: The Congress should provide reasonable time lines and resources for CMS to develop and test regulations thoroughly before implementation.

Constant change will complicate any system because new regulations must be developed and will interact with previous regulations in possibly unanticipated ways. Congress could be less prescriptive in its legislation and leave CMS more leeway to implement policies according to a schedule that allows the agency t h e to test regulations before putting them in effect. Poorly conceived regulations create a demand for Congress to change policies, which in turn results in more prescriptive laws and further changes in regulation. When appropriate, CMS should test regulations before putting them into effect for an entire industry. Time should be allowed for proper development and consultation with industry so that the likely impact of regulations can be understood as soon as possible.

Recommendation *6:* CMS should eliminate regulations and other issuances that become obsolete as a result of program changes.

The continuing move to prospective payment creates complexity and a challenge for the program to make accurate payments. However, the data collection burden might be lessened because some of the data is no longer needed, and some of the instruments are too complex. Outdated data collection requirements illustrate the larger point that as the program changes, regulations, manuals, instructions, and other issuances become obsolete. CMS should develop a sunset mechanism to eliminate obsolete regulations.

For example, as new prospective payment systems are implemented, regulations and other issuances that supported the previous payment mechanism and are now obsolete should be removed. Congress may have to take legislative action to eliminate obsolete requirements if they are specifically called for in law.

Recommendation 7: The Congress should appropriate the necessary resources for CMS to acquire new technology that would simplify administrative processes and improve information exchange with **program participants.**

Some of today's burden could be eliminated by using new technology to modernize program administration. Examples include increasing use of *the* Internet for communication, taking advantage of the Health Insurance Portability and Accountability Act of 1996 billing standardization, and using electronic medical records.

Medicare will remain a complex program because much *of* the complexity is irreducible. However, complexity stemming from difficulties in information sharing and from coniplex payment rules may be made less of a burden on providers and plans through more modern information systems. Developing better systems is a long-temi opportunity that CMS should be given the resources to pursue. ■

CHAPTER 1

Medicare program complexity

Certain aspects of Medicare would make it surprising if the program were not complex. The most basic are the program's size and scope, the fiduciary responsibility of running a public program, the need to protect beneficiaries, and the need to ensure high-quality care. We also examine two other sources of complexity: the program's origin, and the difficulty of coping with rapid changes. Finally, to provide some context, we briefly examine the burden of regulation from the Medicare program, compared with that associated with other payers.

Complexity resulting from the size and scope of the Medicare program

The large size and broad scope of the Medicare program make it complicated to administer and amplify the effects of its rules and regulations on plans, providers and beneficiaries. Purchasing health care for a large number of beneficiaries with different health care needs, in different geographic areas, and from a broad an-ay of providers will inevitably be complicated. At the same time, because the program is so important to many providers and beneficiaries, any burden caused by complicated processes will be noticed.

Size of the program

One of the most salient features of the Medicare program is its sheer size. Measured in terms of the money it spends, the number of beneficiaries it serves, or the number and type of people and facilities that provide health care services to program beneficiaries, Medicare is the biggest health care program in the country.

Spending

Medicare spent about $238 billion in 2001 (CBO 2001), accounting for about 13 percent of the federal budget and about 19 percent of total national spending for personal health services. The prograni spends an average of about $5,950 per beneficiary annually, but the distribution of spending is skewed. For example, 15 percent of beneficiaries accounted for more than 75 percent of Medicare spending in 1997. To manage the program, CMS spends less than 2 percent of benefit outlays, compared with administrative spending of 12 percent and more by private insurers (HCFA 2000).

Beneficiaries

Medicare serves nearly 40 million beneficiaries across the nation, more than twice the number covered by the largest private health insurance company.[1] Of the 40 million, 35 million are aged and the others are disabled or have end-stage renal disease (ESRD). The average age of beneficiaries has increased since the beginning of the program; about 11 percent of aged beneficiaries are now over 85.

Medicare beneficiaries live and seek health care in all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and other U.S. teintories. Lnaddition, compared to the general population a higher percentage of aged beneficiaries live in the most rural areas.

[1] Aetno hod 17.5 million **health** core members as of September 30, 2001

TABLE 1-1

Entities recognized for payment in Medicare

Hospital inpatient settings
- shod-term acute care hospitols
- psychiatric hospitols
- cancer hospitols
- children's hospitois
- rural referral hospitals
- Medicore dependent hospitols
- sole community hospitals
- critical access hospitols

Ambulatory settings
- hospital outpatient departments
- rural health clinics
- federolly qualified heolth clinics
- community mental health centers
- ambulatory surgical centers
- physicion offices
- community health centers
- Indian health service facilities

Post-acute settings
- skilled nursing facilities
- home health agencies
- long-term care hospiiols
- rehabilitation hospitals

Other fee-for-service settings
- durable medical equipment suppliers
- ornbulonce service suppliers
- diagnostic testing facilities
- end-stage renal disease facilities
- clinical laboratories
- mammography screening centers

Non-fee-for-service settings
- Medicare+Choice organizations
- cost health maintenance organizations
- Program of All-inclusive Core for the Elderly (PACE)
- hospices

Source Centers for Medicore & Medicaid Services website [www hdo gov], October 2001

In addition to the complexity created by the number and geographic diversity of beneficiaries, other characteristics of the population magnify the challenge of administering the program. Medicare beneficiaries are more likely than others to have greater health care needs, be in fi-ail condition, have cognitive impairments, and reside in nursing homes. Many, particularly women, live alone and may be either socially or geographically isolated. In addition, aged and disabled beneficiaries tend to have lower incomes; about 17 percent of beneficiaries are dually eligible for Medicare and Medicaid (HCFA 2000). Assuring that beneficiaries understand the rules and limits of the program, their supplemental insurance options, and their health care needs is challenging.

Providers, suppliers, and plans

To provide health care for beneficiaries, Medicare contracts with about 650,000 physicians, 6,000 hospitals, and thousands more providers and suppliers of other types nationwide (GAO 2001a, Berenson 2000). In addition, it contracts with some 1S0 health plans to provide care through Medicare+Choice (M+C).[2] The Congress has defined a broad array of entities recognized for payment in the Medicare program (some of which are defined as distinct only in the Medicare program), many of which are shown in Table 1-1.

[2] Number of heolth plan contracts os of September 1, 2001.

The number and myriad types of providers and suppliers, their geographic dispersion, and the dynamic nature of technology and the practice of medicine make administering the Medicare program complex and vulnerable *to* fraud and abuse. Medicare must enroll each provider and process the 900 million claims submitted by providers each year (GAO 200 1b). Each type of provider is paid through a complex payment system that is subject to various adjustments and updated annually through a process that attempts to take into account the dynamic nature of the health care field.

Managing the M+C program, in which Medicare contracts with health care plans to provide all covered health care services to beneficiaries, presents a somewhat different set of administrative challenges. Medicare must set comprehensive payment rates by county and modify them to account for the demographic and health status of the individuals that enroll in plans. In addition, under M+C, the Centers for Medicare & Medicaid Services (CMS) must collect information (including data on premiums and quality) from plans each year and monitor how the plans market themselves to beneficiaries.

Regulators and administrators

A vast array of regulators and administrators interacts with health plans, providers, suppliers, and beneficiaries to develop and carry out Medicare regulations. Their roles range from educator to enforcer. To complicate matters, some actors are government agencies and others are contractors to the government; some have nationwide and some have regional responsibilities; some are within the Department of Health and Human Services and some are not. Table 1-2 displays these regulatory and administrative entities and their regulatory functions. Excluded from the chart is the Congress, whose statutoiy language is the cause of much of Medicare's complexity. Entities in the chart must interpret the Congress's legislative intent and then develop, implement, refine, administer or enforce the resulting regulations. The complexity of this system contributes to burden by making it difficult for providers and beneficiaries to know whom to call or where to get information, guidance, or answers.

Scope of the program

The broad scope of the Medicare program contributes to its complexity and would be difficult to diminish. The Medicare prograni must regulate:

- who is eligible to enroll,
- which services are covered,
- who can provide services,
- the conditions under which providers, suppliers, and health plans can participate, and
- how payment should be made.

The result is Medicare statute that takes up more than 600 pages of the U.S code, and regulations that comprise two volumes of the Code of Federal Regulations. In addition. myriad other issuances of CMS and its contractors (discussed in Appendix **A),** accompanied by the commentary provided by newsletters and professional organizations, create a flood of paper for providers to sort through. For example, a home care agency we visited reported that there have been 8,000 pages of regulations and other issuances since July 1999 (Abt Associates 2001).

TABLE 1-2

Regulatory and administrative entities

Entity	Function					
	Promulgate	implement	Interpret	Refer or enforce	Educate	Evaluate or investigate
CMS [central office)	✔	✔	✔	✔	✔	✔
CMS (10 regional offices)		✔	✔	✔	✔	✔
CMS software venders						
Claims processing contractors carriers, fiscal intermediaries, regional home health intermediaries, durable medical equipment regional carriers		✔	✔	✔	✔	✔
Carrier advisory/fiscal intermediary advisory committees			✔			
Program sofeguard coniroctors 11 task order contracts issued to various entities far pre-/past-payment reviews and data analysis/ data mining			✔	✔	✔	✔
Peer review organizations				✔	✔	✔
State health insurance programs			✔	✔	✔	✔
Department of Justice, regional U.S. attorney's offices			✔	✔	✔	✔
Department of Health and Human Services, Office of the Inspector General			✔	✔		✔
Federal Bureau of Investigation			✔	✔		✔
Courts and boards			✔	✔		
Social Security Administration		✔	✔			

Note: CMS (Centersfor Medicare & Medicaid Services), Courts and boards (includesadministrative law judges; Provider Reimbursement Review Board, Medicore Geographic Classification Review Board; Deportment of Healthand Human Services, Departmental Appeals Board. Appellate Division; Courts: state, U.S. District, U.S. Appeals, U.S. Supreme).

Source MedPAC.

Genesis of current provider-based criteria

Since Medicare's mception, some facilities (primarily hospitals) have owned and operated other facilities such as home health agencies and rural health clinics. Before implementation of prospective payment systems, such affiliations did not increase payments because payments were cost based. Medicare law did not use or define the term "provider-based" and there was no statutory requirement to establish explicit criteria for determining provider-based status. With the advent of prospective payment systems and increased payment for provider-based facilities, the Centers for Medicare & Medicaid Services (CMS), then the Health Care Financing Administration (HCFA), had to establish criteria. The delicate balance between CMS' administrative authority and the Congressional intervention that followed, as illustrated below, highlights the complexity of rulemaking in a dynamic and political environment.

- August **7,1996:** HCFA issued Program Memorandum A-96-7. which compiled general instructions for the designation of provider-based status for all facilities or organizations from previously published documents.
- **October 1999:** HCFA "manualized" the instructions in program manuals.
- **April 7,2000:** HCFA published a final rule governing provider-based status, slated for implementation October 10,2000. Providers voiced opposition to and concern about many aspects of the final rule.
- **October 3,2000:** In response to provider concerns, HCFA published a notice delaying the effective dates of the provider-based rule to January 10,2001 and allowed one year from that date to phase in the implementation.
- **December 21,2000:** Congress responded to facilities' concerns with narrowly crafted statutory provisions in the Benefits Improvement and Protection Act of 2000 (BIPA).
- August **24,2001** : CMS published a significantly altered proposed rule that implemented BIPA provisions to grandfather certain facilities, delayed the implementation date, and modified other criteria of the proposed rule.
- **November 2001:** CMS is expected to publish a final rule implementing the revised criteria for provider-based facilities. ■

Developing policies to answer eligibility, coverage, and payment questions and devising regulations to implement the policies has produced much debate and a dense web of regulation. Policies are interrelated and must adapt to a dynamic marketplace and rapid changes in health care technology and delivery. In addition, as shortcomings of Medicare regulations have become apparent, policymakers have tended to adopt more detailed and prescriptive regulations. For example, when policymakers suspected that some providers were opening "hospital-based" clinics far from hospitals to maximize reimbursement (because "hospital-based" clinics receive increased Medicare payments), they responded by delineating a complicated set of definitions of "provider-based." Because so many variations in the marketplace need to be addressed by regulators, CMS has published more than 100 pages in 3 separate Federal Register notices to explain 3 pages of proposed rules governing provider-based facilities.

Who is eligible for coverage?

Eligibility criteria for Medicare are based upon age. disability, and work history. Much of this is specified in statute, but regulations must define "work history" and "disability". Regulations also govern other enrollment issues, such as how to assess penalties for delayed enrollment in Part B and how to conduct enrollment in M–C plans. The mechanics of enrollment in Medicare, as well as determinations about disability status, are carried out by the Social Security Administration.

What services and supplies are covered?

Although the Congress specifies that all medically necessary care furnished by contracting providers should be covered within the general scope of the benefit package outlined in statute, program administrators must make countless coverage decisions every day. For example, some procedures (such as organ transplants) are only covered for beneficiaries who meet certain health status criteria, lung volume reduction surgery is only covered for beneficiaries participating in clinical trials. CMS coverage regulations, determinations made by the Medicare Coverage Advisory Committee, local medical review policies, and appeals rulings guide administrators in making these decisions.

Efforts to define covered services are complicated by the dynamic nature of health care services and technology, the decentralized system of claims processing, limited resources to evaluate new technologies, and the political environment surrounding these decisions.

Who is qualified to provide care and supplies to Medicare beneficiaries?

Medicare, like any other health care insurer, must determine whom it will contract to provide care and supplies to its beneficiaries. Defining participation qualifications (known as conditions of participation), collecting reliable and timely information on providers, and enforcing compliance are critical to promote high-quality care. For example, Medicare must ensure that its providers are licensed.

The provider enrollment process helps to ensure that only qualified individuals and entities receive reimbursement for services furnished to beneficiaries. In addition, a provider's geographic location and facility type may have direct bearing on its payment amount.

Physicians have complained that the enrollment process takes too long and that it must be repeated each time doctors change employers or make other practice changes. Enrollment is a decentralized process in which providers must complete separate copies of HCFA Form 855 to enroll in each federal program they intend to bill (for example, the civilian health and medical program of the uniformed services, the Public Health Service, the Indian Health Service, and Medicaid), including separate applications for billing Medicare Parts A and B. The form itself (HCFA 855) is considered overly complex. In contrast to durable medical equipment suppliers, whose enrollment is administered under one contractor nationwide, each local contractor administers its own physician enrollment processes.[3]

CMS recently announced steps to simplify the enrollment form and intends to process 90 percent of enrollments within 60 days.

How should payment be made?

Policyinakers must determine which methods the Medicare program will use to pay providers, suppliers, and health plans. At the inception of the program, Medicare paid providers basedupon costs and their usual, customary, and reasonable (UCR) charges. However, this payment method provided no incentive for efficiency, and costs and payments rose as a result. The Congress reacted by changing the basis for payment and the program moved toward prospective payment systems (PPSs), which pay a set price for a bundle of services, and are intended to reward efficient providers. The PPS for inpatient care, for example — introduced in 1984 — pays hospitals a set amount according to the principal diagnoses for a hospital stay, regardless of the actual costs for individual cases. Now, nearly all sectors are under some fomi of PPS or a fee schedule, including skilled nursing facilities, hospital outpatient departments, ambulatory surgical centers, home health agencies, and physicians. However, each payment system requires its own regulations, rules, and data gathering.

Setting prices administratively through prospective payment systems is inherently complex because it is difficult to know providers' true costs of efficiently caring for Medicare beneficiaries. To arrive at payment rates that approximate market prices and cover providers' long-run costs, payment methods must account for the individual circumstances confronting providers, such as local market conditions and the mix of coniplicated and simple cases. Adding to the complexity is that Medicare payment regulations have attempted to achieve multiple objectives that private payers do not share, including supporting physician education and improving access to care in rural areas.

The result is separate regulations specifying payment methods for each type of provider. While payment systems share many of the same fundamental components, each is tailored to the specific resources needed to provide the service. For example, Medicare pays physicians based upon a fee schedule that takes into account their practice costs, professional liability expenses, and work content.

Although the entire rationale and method of payment has changed, the mechanism for paying claims — relying on local contractors — has not. The original rationale for using local contractors was that they could determine local UCR charges and audit the costs of local providers. Neither of those determinations is used under national PPSs, yet the claims payment mechanism has been preserved. A basic contradiction now exists between the payment mechanism and the payment system.[4]

To a great extent, the complexity of Medicare's payment system is linked to the fact that the program directly contracts with providers to provide fee-for-service care and must set prices for thousands of services in every part of the country. If, like the Federal Employee Health Benefits (FEHB) Program, Medicare instead contracted with private insurance plans to provide coverage, CMS regulatory requirements for providers would be reduced.[5] However, when policy experts have explored adopting the FEHB model for the Medicare population, most, including the Bipartisan Commission on the Future of Medicare, have concluded that fee-for-service Medicare is needed to guarantee beneficiaries the option of retaining their current plan. Even under this vision for a reformed program, many of the existing regulatory requirements would remain.

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4 Even where there has been consolidation of contractors (for example one carrier now covers 11 states) separate medical directors and carrier advisory committees for each state have been retained and separate claims payment and coverage policies still persist.

5 Presumably, as in the M+C program, a private health plon would perform many of the regulatory functions that CMS currently performs and the providers would still have some regulatory burden.

Complexity resulting from the responsibilities of the Medicare program

Beyond the size and scope of the program, the responsibilities of the Medicare program lead to complexity: the fiduciary responsibility of a public program, the responsibility to protect beneficiaries, and the responsibility to ensure quality.

Medicare's fiduciary responsibility as a public program

Running a public program adds requirements for public decision making and due process to the already difficult fiduciary task of any health insurer. Every insurer needs to establish billing rules to pay contracting providers agreed-upon rates and to prevent paying fraudulent claims. These rules begin with provider enrollment and also cover rules for claims submissions and efforts to stem fraud and abuse. Compared with private insurers, Medicare claims processing is dramatically complicated by the sheer volume of claims and by the structure of claims processing, which relies on multiple contractors such as fiscal intermediaries and carriers. These characteristics directly contribute to a high risk of Medicare fraud and abuse and to the complexity and regulatory burden of the program.

Recent efforts to improve the detection and prosecution of fraud and abuse have raised concern among providers, but of the 650,000 physicians in the program, less than 2,000 physicians are subject to complex medical review each year and the Department of Health and Human Services, Office of the Inspector General (HHS OIG) investigated only a few hundred physicians (GAO 2001a). Nevertheless, the fear of unwarranted fraud accusations is real, and influences providers' perceptions of the burden of the program. Many feel that they cannot win; the program is so complex that they are bound to miss some requirements no matter how hard they try to comply, and the penalty for non-compliance is perceived to be harsh.

In addition to the fiduciary responsibility any insurer has to prevent payment of fraudulent claims, Medicare's identity as a public program leads to additional administrative complexity because the program must maintain a degree of accountability, openness, transparency, and commitment to due process not required of private insurers. Medicare's administrators must conform with laws such as the Administrative Procedure Act (APA), Federal Advisory Committee Act (FACA), Federal Civil Service laws, the Freedom of Information Act, the Government Performance and Results Act, and the Paperwork Reduction Act, among others. Most of these laws have no analogs in the private sector.

For example, the Administrative Procedure Act specifies, among other things, how agencies must conduct rulemaking. The Act generally requires public notice and the opportunity for participation by interested persons. FACA governs how Medicare administrators can seek advice or recommendations from outside entities, and requires that committees be established only after public notice, that they have a clearly defined purpose, that membership be balanced in its point of view, and that meetings be open to the public.[6] Furthermore, civil service laws dictate hiring and firing practices as well as salary structure for federal employees. While serving an important purpose, these laws restrict CMS's ability to nimbly respond to new resource or expertise requirements. Indeed, other federal agencies have more flexibility to offer competitive salaries to attract top advisors (DeParle 2001).

[6] According to a former administrator, if CMS wanted to confer with industry groups to resolve issues in developing a regulation, it would need to charter a federal advisory committee, an action that requires financial disclosure forms and notices in the Federal Register, among other requirements.

Coverage appeals and other decisions are also subject to a higher level of due process than are those of private entities. For example, if an employee appeals to her self-insured employer for coverage of a needed medical service, the employer can consider the request with less public scrutiny and under a more liberal time frame than Medicare can.

Finally, Medicare is ultimately govenied by Congress in a political environment. The legislative process is subject to political pressures that do not often apply to decisions made by a private insurance company. This process allows the public, through its representatives, to participate in shaping a vast and important program. Sometimes, however, Congress is so prescriptive that even when administrators realize there are problems in implementing the law, they cannot fix them.

A current example concerns the sustainable growth rate (SGR) mechanism for physician payment. CMS has recognized that the mechanism will result in wide swings in the update factor for physician services and that the result for 2002 will be a 5.4 percent negative adjustment. However, because the fonnula for the SGR is set in statute, the agency has little latitude to make changes.

Medicare's responsibility to protect beneficiaries

Medicare regulations require various provisions for beneficiary education and protection. These range from requiring that CMS distribute a handbook explaining the program to beneficiaries to setting procedures for appeals and grievances. Through the enrollment process, providers attest to the basic educational and licensure qualifications required to bill the program for furnishing services to Medicare beneficiaries. In addition, Medicare statute and regulations require that participating providers and plans adhere to other federal health laws, including privacy and confidentiality requirements in the Health Insurance Portability and Accountability Act, Emergency Medical Treatment and Active Labor Act requirements governing anti-dumping, and laws encouraging the use of advance directives.

Medicare's responsibility for ensuring quality

Policymakers have become increasingly interested in promoting high-quality care for beneficiaries. In addition to establishing and enforcing conditions of participation, Medicare uses peer review organizations to help providers improve the quality of care. However, measuring quality in health care is difficult. Few outcome measures exist, and using them requires adjusting for the health status of patients before treatment. Using process measures is difficult when care is delivered in a fee-for-service environment by unrelated providers and no one entity has ownership for the whole process. In the M+C program, plans have expressed concern about the extensive set of requirements for quality assurance and quality improvement currently in place. Attempts to measure quality, let alone improve it, add coniplexity to the program.

Complexity resulting from the way the Medicare program began

The childhood shows the man
As morning shows the *day.* — *Milton, Paradise Lost*

Some of the complexity of the Medicare program can be traced to the way in which the program was established. Part **A** of Medicare grew out of a series of legislative proposals to cover hospitalization for the aged that had been under discussion by policymakers and the American Hospital Association in the early 1960s. Part B emerged fi-om a proposal by Congressman Bymes (R-Wisc.) for a voluntary coverage plan. (The actual legislation for Part B was written over one weekend and was based on Aetna's federal employees plan [Gluck and Reno 2001].) The combination of the two parts, although in some sense a compromise to generate support, was a giant step forward in health care coverage for the elderly and was much more comprehensive than the hospital-only coverage that had been proposed earlier.

Meanwhile, the American Medical Association, which was opposed to the proposal for hospital coverage, offered a state-run, means-tested program as an alternative. Instead of being adopted as a substitute, that proposal was included as well and became the basis for Medicaid.

No overarching vision or coherent undergirding principles linked the two parts of Medicare or Medicare with Medicaid, nor did the Congress make any attempt to rationalize cost sharing or incentives resulting from the two parts of Medicare. Any resulting discordances remained in the programs and some of today's complexities are reverberations of those original discords.

Complexity from the Part A-Part B split

The Part A-Part B split results in a series of complexities in the program starting with eligibility for enrollment. Part **A** was conceived of as a compulsory program accepting anyone eligible for Social Security retirement benefits and financed by payroll taxes (much like Social Security). Part B, on the other hand, was conceived of as a voluntary program; enrollees would make a one-time election into the program which would be financed partly by beneficiaries and partly by general revenues.[7] (When the program began the premium was split 50-50; now it is 25 percent from beneficiaries and 75 percent from general revenue.) The vast majority of beneficiaries are enrolled in both Part A and Part B, although some are enrolled only in one part. This means that every provider and plan must establish not only that patients are eligible for Medicare, but in which part or parts they are enrolled.

As an example of the complexity that results, consider enrollees in the M+C program (Part C of the Medicare program) who have only Part B Medicare coverage and have been "grandfathered" into the program. Because of those few enrollees — about 1,100 out of 5.5 million — some M+C organizations must calculate and submit a Part B-only Adjusted Community Rate Proposal (ACRP) filing in addition to their usual ACRP filings.

[7] Beneficiaries who did not contribute to the Social Security system, such as some state and local government employees, some federal employees, and railroad workers, must pay an additional premium to enroll in Part A.

The two-part split also adds complexity for beneficiaries because they must choose when to start Part B coverage and must be aware of the perils of delaying that election, whereas Part A coverage starts automatically. Each part also has completely independent coinsurance and deductibles. For example, paying the $100 Part B deductible has no effect on the size of the Part A deductible for inpatient hospital services, and the 20 percent coinsurance for most services under Part B has no analog in Part A. Furthennore, some services, such as home health, are split between Parts A and B. Physicians' services are under Part B even if the beneficiary is in a facility under Part A. All of this compounds the difficulties for beneficiaries trying to interpret an explanation of Medicare benefits (EOMB) form or Medicare summary notice (MSN) form and attempting to figure out how much they owe and whether claims have been properly paid. It also makes it difficult for beneficiaries to assess choices for supplemental coverage and to choose whether to enroll in a M+C plan rather than remain in the traditional fee-for-service program.

Claims payment was also complicated by the original design of the program because Medicare established contracts with two sets of contractors. Fiscal Intermediaries to pay Part A and Part B institutional bills, and carriers to pay only Part B claims.

Complexity from the contracting arrangements

Those who designed the program originally intended that Medicare's primary interface with providers and—to some extent, beneficiaries—would be insurance companies, rather than the federal government. This may have been a way to placate those worried about socialized medicine, a worry that also probably resulted in the provision in Medicare law that prohibits any federal interference in the practice of medicine. At least one fiscal intermediary and one carrier were chosen for each state and each contractor was free to use whatever system it wanted to pay claims.

Policymakers considered reliance on local contractors to be a strength of the original program design. After all, most providers were to be paid based on their costs and UCR charges in the local area. In addition, policymakers thought that "acceptable practice" differed across the country and that procedures might be standard practice in one area but not in others. Using local contractors familiar with local practice standards was a way to recognize this variation and allow for it in payment.

The legislation also placed some unusual contracting limitations on the program. The Part A fiscal intermediaries are nominated by providers, even though they are in charge of paying those providers for services rendered to Medicare beneficiaries. Carriers for Part B were designed to be local organizations. Their contracts are normally automatically renewable and exempt from any provision of law requiring competitive bidding.

Early in the program, administrators recognized that using insurance companies to pay claims was not working as well as anticipated. In some cases, the companies lacked both capacity and experience (NASI 2001). As claims processing has become more automated, payment systems less cost based, and multi-state providers more common, the basic contradiction of a national program and local claims processing has become even more evident. Because the reality of what is policy for providers is what the automated claims processing systems pay, the logic embedded in the code for processing claims is all important. Recognizing that, CMS has attempted to standardize claims processing systems and has now migrated fiscal intermediaries to two standard systems and carriers to four standard systems. However, contractors still have latitude to establish local medical review policies and their attendant automated system edits, with the result that the same claim may sail through one carrier and be rejected by another. Also, because some system edits may be intermittently turned off due to workload considerations, the same claim may meet different fates even with the same carrier.

Complexity resulting from coping with change

The Medicare program has become more complex with changes in the goals of the program. laws and regulations. the health care world, and the beneficiary population it serves. Because Medicare regulations are continually rewritten, reinterpreted, and augmented, providers have difficulty keeping up—both small providers that lack extensive administrative resources as well as large, diverse facilities affected by many simultaneous changes. Health plans in M+C face a similar challenge.

Changing goals

The original Medicare legislation aimed to save elderly beneficiaries from ruinous hospital and physician bills. However, the legislation limited covered hospital days and did not impose out-of-pocket limits to beneficiary liability: the goal was not total protection from catastrophic expenses. At the same time, Medicare was an insurance program for acute medical expenses, not a pre-paid health care program, with sizable coinsurance and deductibles and no coverage for preventive services such as annual physicals. Some coverage has since been instituted for preventive measures (for example, screening tests for breast and colon cancer) fiu-ther complicating rules about the number and frequency of covered services.

Other goals incorporated into the program have brought about more regulation, including encouraging medical education; preserving access to care by protecting providers with certain characteristics, such as rural location or service to indigent patients; and providing private sector choices.

Changing laws and regulations

Although the Medicare program has undergone many changes during its more than 35 years of existence, the most dramatic changes have occurred over the past several years. The Balanced Budget Act of 1997 included more than 700 specific directives to HCFA (Abernathy 2001j, including creation of the M+C program and new PPSs for skilled nursing facilities, home health agencies, and services in hospital outpatient departments. Following quickly on the heels of this massive legislation were the Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000. Each of these laws amended the BBA and added new regulatory requirements. In addition, other laws, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), imposed administrative and privacy standards that many in the industry find burdensome.

TABLE 1-3

Medicare contractors

Contractor (number)	Responsibilities
Claims odrninistration controctors (56) ▪ carriers (Port B claims) (20) • fiscal intermediaries (Port A claims) (28) • regional home health intermediaries (4) • durable medical equipment regional corriers (4)	→ moke coverage decisions and establish local medical review policies → generate noiices to beneficiaries exploining benefits → identify cloims mistakenly billed to Medicore → operate fraud units ond develop and refer coses to low enforcement agencies → identify instances or patterns of inappropriate billing
Program safeguard contractors (11) ▪ CMS issues task orders to contractors on a functional basis	→ on-site reviews to determine compliance with corporate integrity ogreements → postpayment data onalysis, statistical onalyses and trending activities on claims → perform all progrom integrity functions, including prepayment ond postpayment review, for a DMERC → develop national paid claim error rotes by contractor, benefit category, and provider type through independent review of a random sample of claims → maintain automated system edits (correct coding initictive) used by all claims administration controctors → created in BBA
Peer review organizations (37)	→ determine whether services ore reasonable and medically necessary → check validity of diagnostic ond procedural informotion supplied for payment purposes → evaluate completeness ond odequocy of hospital care provided → evaluate quality of services
Qualified independent controctors • minimum of 12 controctors required by BIPA, effective October 2002	→ review redetermination decisions for Port A ond B claims → external to claims administration Contractors

Note: CMS (Centersfor Medicore & Medicoid Services), BIPA (Medicore, Medicoid, and SCHIP Benefits Improvementand Protection Ad of 20001, DMERC (durable medicalequipment regional carrier), BBA (Balanced Budget Act of 1997). Fiscal intermedioriesalso pay some institutional bills under Port B.

Source: CMS.

The new laws have also requirednew contractors to help implement them. As Table 1-3 shows, the types of contractors have now expanded well beyond the original Part A fiscal intermediaries and Part B carriers. Attempts to specialize by function, while alleviating some variation, create new boundaries and bamers to communication. The program now has multiple contractors divided by geography, entities covered, and function.

Changing health care world

Many factors — including changing technology, demographics, reimbursement policy (such as capitated payments), and market dynamics — have led to changes in the organization and structure of the health services industry. The advent of national chains of hospitals, nursing homes, dialysis facilities, and others and consolidation among health plans has altered the dynamic of health care and the loyalty and trust of patients and regulators, increasing the desire for more extensive regulations and enforcement.

When Medicare began, payments for inpatient hospital stays and physician services accounted for most expenditures. Now other settings, such as hospital outpatient departments, ambulatory surgical centers, skilled nursing facilities, and home health agencies, have increased in importance.[8] In addition, health care technology has grown and changed rapidly. Imaging technologies, arthroscopic surgery, coronary artery bypass grafts, and angioplasties are all examples of technologies that did not exist or were of very limited availability at the beginning of the Medicare program. All had to be brought into the program and their appropriate use and payments determined.

[8] In some coses, technology has allowed proceduresformerly limited to inpatient stays to be performed in on ambulatory setting, In oddition, Medicore reimbursement policy moy have mode some settings more lucrative than others.

The massive movement toward managed care by insurers and the consolidation and increased predominance of national firms in that industry has also had an enormous impact on the organization of health care. Not long ago, it was widely anticipated that managed care organizations would continue to grow while holding down health care costs. But largely due to the consolidation of providers, such as mergers among hospitals, providers have regained leverage in the marketplace and are either demanding better terms or refusing to join managed care networks (Strunk et al 2001). At the same time, consumers are demanding more flexibility in the choice of providers. The result is slower growth in more highly integrated managed care options, increasing demand for less tightly structured options, and escalating premiums. As the entire marketplace has grown more unsettled, policymakers have increased regulation and exceptions to help ensure access. The fast changing nature of the marketplace has resulted in increased anxiety and may have contributed to a concomitant increase in the pace of regulation.

Changing beneficiary population

The changing beneficiary population also has increased the complexity of the program. The most obvious change was the inclusion in 1972 of those eligible for Social Security disability benefits and people with ESRD. In addition, changes in the aged population (such as the increasing proportion of beneficiaries over age 85) and the services they use (such as procedures formerly limited to relatively young beneficiaries) require the program to deal with an ever broader range of issues.

Another change for beneficiaries has been the availability of supplemental insurance through their former employers or the Medigap market. In 1997, 86 percent of beneficiaries had supplemental coverage (including those with Medicaid). If the original program was predicated on the inclusion of deductibles and coinsurance to influence beneficiaries' behavior, the advent of supplementary policies negated that premise by providing first-dollar coverage for most services. The interaction between Medicare and supplemental insurance introduces other forms of complexity. It makes it more difficult to forecast the likely effects of changes in incentive structures, because different segments of the beneficiary population have different levels of supplemental coverage. It also creates an additional step in the claims administration process and uncertainty among beneficiaries over who *to* ask for reimbursement.

Complexity and burden

If the complexity in Medicare only made the program difficult to administer, it would not be the subject of such concern in the Congress; the concern stems from how the complexity affects providers and beneficiaries. When assessing the burdens of Medicare requirements, it is worth considering whether there is a better alternative. Can any large, national system provide health care coverage in a way that is not burdensome to providers and beneficiaries? We examine this question by briefly comparing how requirements imposed on providers and beneficiaries by the Medicare program compare with those of other payers, such as private insurance companies and other government programs. We also look at how Medicare and other payors balance different means for accomplishing specific program functions.

We note that comparisons between Medicare and other payors may be somewhat misleading, because other payors can often assume that providers are meeting requirements imposed by Medicare. Thus, the unique requirements of other payors may not replace Medicare's requirements but rather add to them. Furthennore, to encourage provider participation, other payors may be forced to moderate their requirements in some markets.

Comparison with requirements imposed by other payers

Medicare is considered to be particularly burdensome in its requirements for documenting evaluation and management visits, applying diagnosis codes to all laboratory tests, filling out Medicare secondary payor fomis, and providing advance beneficiary notice of coverage forms. As an example, Medicare providers and beneficiaries express frustration with Medicare's requirement that providers furnish advance beneficiary notice forms to inform beneficiaries that services they receive may not be paid for by Medicare. The frustration is that beneficiaries cannot receive advance determinations from Medicare carriers about covered services and therefore cannot know if they may be liable for payment. Private insurers or health plans usually have clear mechanisms for an advance determination about what is covered under a patient's policy or plan.

Interestingly, despite these complaints, in a 1999 MedPAC survey physicians reported that the paperwork and administrative billing hassles of health maintenance organizations (HMOs) or other capitated plans were worse than those under traditional Medicare. More than half of physicians called the paperwork burden of HMOs and other capitated plans a very serious problem; 30 percent of doctors placed Medicare's administrative burden in the same category (Project HOPE 1999). This finding is consistent with results from a similar study by the Physician Payment Review Commission in 1994. We also heard consistently from providers in site visits that Medicare is considered one of the better payors in terms of timeliness in paying clean claims.

Compared with some other payors, Medicare's administrative burden may appear less womsome to physicians. However, another aspect of the program raises the stakes for providers and may make the program appear much more burdensome. If providers make a mistake in complying with Medicare's administrative requirements, in addition to not being reimbursed they also can face the risk of other sanctions if investigators interpret their actions as fraudulent rather than simply mistaken. Where a private plan may have an investigative arm to ferret out fraudulent claims, Medicare has well-fimded investigators from the HHS OIG, the Department of Justice, and U.S. Attorney's offices in *every* state. Providers are constantly reminded by a burgeoning compliance industry and urban legend that the jeopardy to which they are exposed by Medicare billing mistakes may result in extrapolated overpayment demands, criminal prosecution, or the imposition of civil monetary penalties and corporate integrity agreements.[9]

[9] Extrapolation refers to the proctice whereby confroctors review a small set of cloims for a particular provider ond if errors ore noted in some percentoge of the sample, extrapoiate thot percenioge to the entire set of claims the provider has submitted within some time period ond calculate overpoymeni amounts accordingly. Modern statistical methods might improve the occurocy of extropolotion. Currently, o provider con ask that a statistically significant sample of cloims be token but most are loathe to do so. Legislation is pending that changes specific extrapolation procedures.

In fact, the OIG investigates a small fraction of the more than 700,000 providers and suppliers that annually submit more than 900 million Medicare claims.[10] Although only a nominal number of providers are investigated each year, the savings to the program are substantial and the behavioral response and fear elicited in the provider community undeniable. The perception of burden stemming from liability under the Medicare statute has no analog in the private market, where insurers lack the authority or resources to impose such sanctions and few, if any, hold a market share comparable to Medicare.

Comparison with requirements in other government programs

Although similar in size and broader in scope than Medicare, Medicaid (which provides a full range of services, including long-term care and prescription drugs) is a smaller part of many providers' revenues than Medicare. States have substantial flexibility to run their Medicaid programs under broad federal guidelines and use this prerogative to establish eligibility standards, set payment rates, and determine the type, amount, duration, and scope of services. In 1999, more than **42** million people were enrolled in state Medicaid programs, but more than half were enrolled in an HMO or other partially capitated managed care arrangement, compared with a participation rate of less than 14 percent in the M+C program. Accordingly, discontent with Medicaid tends to focus on inadequate payment rather than regulatory burden.

Balance

To achieve their goals, all regulatory systems must achieve a balance among various means for accomplishing specific program functions. Where that balance is struck can affect the burden of the regulatoiy system on the regulated entities. Below, we examine how Medicare and other payors strike balances in three program functions.

Claims payment: balancing customer service and enforcement

Any regulatory system must balance providing acceptable customer service and enforcing the rules of the program. For example, the Customs Service seeks to minimize inconvenience to freight shippers and at the same time prevent contraband from being smuggled into the United States. It could stop every truck entering the country, unload the cargo, and go through it piece by piece —an enforcement-heavy approach. However, if it took such an approach, lines of trucks would accumulate at the border, leading to massive delays. This would be very poor customer service. Instead, the Customs Service uses automated tools to decide which trucks to pre-approve and which to search. Most trucks are not searched; those that are searched have been deemed high risk. The Customs Service also searches some trucks at random.

[10] In FY 2000, the OIG conducted or participated in 2,597 health care cases, of which fewer than 600 led to either criminal conviction or successful civil recoveries (OIG 2001).

The Medicare program must balance paying claims in a timely way (customer service) and preventing fraud and abuse (enforcement). Most claims are considered "clean" and processed rapidly. Some are denied and some are reviewed before payment: when these things happen, the system can seem arbitrary and burdensome to the providers. Even if a claim is initially paid rapidly, the claims administrator may retroactively determine there has been an error, assess the provider for an overpayment and in some cases request prosecution for fraud. This latter pattern (a process sometimes referred to as "pay and chase") can come about as a result of post-payment audits or analyses of patterns of use, or as a result of a fraud complaint. This multidimensional approach adds complexity and can appear particularly onerous to providers. In recent years, as reports of fraud against the program multiplied, the Congress thought the balance had shifted away from enforcement. As a result, provisions in the Health Insurance Portability and Accountability Act of 1996 gave more financing and broader authorities to the Department of Justice and the HHS OIG for fraud and abuse enforcement efforts. Providers now think the balance has shifted too much toward enforcement.

Provider participation: balancing up-front requirements and back-end rigor

To ensure program integrity, Medicare also must balance up-front requirements for provider network inclusion with back-end rigor of claims processing and enforcement. The program could have strict conditions for participation and then lessen the intensity of claims review as providers build up track records of good behavior. Instead, the Medicare program relies heavily on claims processing and the medical review process to identify problems and tends to treat all providers the same, regardless of past performance. Some private-sector plans take the opposite approach: they rely more heavily on provider selection and will not retain providers in the network if utilization goals are not achieved. The current balance in the Medicare program is less reliance on strict participation requirements and more reliance on claims and medical review, placing more burden on current providers.

Coverage of services: balancing pre-certification and retrospective adjudication

Medicare must balance retrospective adjudication of claims with pre-determination (a determination of coverage before a service is performed). Unlike many private plans, which provide for or even require pre-determination, Medicare will not give a binding determination before a service is provided and instead solely uses retrospective adjudication of claims. At the same time, regulations require that beneficiaries be informed of the possibility of non-coverage through advance beneficiary notices (ABNs). Having no pre-determination adds to the complexity of decision making for beneficiaries and makes it difficult for providers to explain to beneficiaries which services are covered. ■

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CHAPTER 2

Simplifying the program: recommendations

RECOMMENDATIONS

1 CMS should move to a standard nationwide system of claims processing and eliminate local descriptions of policy and regulation. The Congress should allow CMS to contract as necessary to implement a standard system efficiently.

• YES: 13 • NO: 1 • NOT VOTING: 1 • ABSENT: 2

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2 The Medicare program should provide timely, binding written guidance to plans and providers. Plans and providers that rely on such guidance should not be subject to civil or criminal penalties or be required to refund related payments if that guidance is later found to be in error.

• YES: 14 • NO: 0 • NOT VOTING: 0 • ABSENT 3

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3 CMS should explore ways to reduce routine adniinistrative requirements for plans and providers that demonstrate sustained good performance.

• YES: 15 • NO: 0 • NOT VOTING: 0 • ABSENT: 2

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4 The Secretary of Health and Human Services should work with the Department of Justice to improve consistency and eliminate redundancy in enforcement roles and activities.

• YES: 12 • NO: 0 • NOT VOTING: 0 • ABSENT: 5

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5 The Congress should provide reasonable time lines and resources for CMS to develop and test regulations thoroughly before implementation.

• YES: 13 • NO: 0 • NOT VOTING: 0 • ABSENT: 4

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6 CMS should eliminate regulations and other issuances that become obsolete as a result of program changes.

• YES: 15 • NO: 0 • NOT VOTING: 0 • ABSENT: 2

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7 The Congress should appropriate the necessary resources for CMS to acquire new technology that would simplify administrative processes and improve information exchange with program participants.

• YES: 15 • NO: 0 • NOT VOTING: 0 • ABSENT: 2

'COMMISSIONERS' VOTING RESULTS

Understanding the sources of complexity in the Medicare program is only a first step. In this chapter, we examine the different aspects of the program, determine whether elements in each can be simplified, and identify promising targets for simplification that will lift burden from beneficiaries and providers. We make recommendations where warranted for legislative or administrative actions.

Simplifying fundamental aspects of the program

Some aspects of the Medicare program are fundamental to its very nature. These include the scope of the program, its fiduciary responsibility to taxpayers and beneficiaries, its role in beneficiary protection and education, and its responsibility to ensure the quality of care provided. Because they are fundamental, these aspects would at first appear to be less amenable to simplification than others. Nevertheless, some simplification may be possible.

Size and scope of the program

The size and scope of the program—the large number of beneficiaries, the wide range of covered services, and the variety and number of participating providers and plans—is enormous by any measure. Complexity that arises directly from this scope is to a large extent irreducible. For example, because the program has beneficiaries all over the country, the program must be able to pay providers appropriately in all areas so that beneficiaries can have access to health care. The program also must be able to enroll beneficiaries wherever they live and send them infomiation about the program.

In contrast, private plans can choose where they want to do business and who their customers are. For example, they may choose to cover only large employee groups in urban areas, because marketing to groups is more efficient than marketing to individuals and forming networks is easier in urban areas than in rural areas. The Medicare program cannot make such a choice; instead, it must accept the complexity associated with providing nationwide coverage for all qualifying beneficiaries.

The scope of the program is also influenced by the goals of the program. Currently, Medicare is more than an insurance plan for acute care of the elderly. The program serves not only the elderly, but also individuals with ESRD and the disabled. It covers not only acute care, but also some preventive services. It also provides funds for educating physicians and other providers and for facilities that provide care for the indigent. These additional goals make the program more complex in several ways. For example, the graduate medical education (GME) program requires Medicare to collect data on resident physicians and makes the payment system more complex for hospitals in fee-for-service and M+C plans. GME payments also complicate the political climate because they are concentrated in particular states and hospitals. If mechanisms could be found outside the Medicare program for fulfilling these other policy goals, the program could be simplified, although the regulatory burden associated with those goals might simply be shifted elsewhere.

Alternatively, a more comprehensive goal for the program could be envisioned in which Medicare covered all medical services — including preventive and acute — and provided a catastrophic cap on beneficiary cost sharing. Such a goal could lessen burden on beneficiaries by lessening the need for supplementary coverage. The current benefit design is essentially unchanged from the original legislation and reflects the split between Part A and Part B in its cost-sharing provisions.[1] The complication of the current cost-sharing rules along with the lack of a out-of-pocket cap on beneficiary liability drives many beneficiaries to seek supplemental insurance (86 percent of beneficiaries had supplemental coverage in 1997). Such coverage increases complexity for beneficiaries, who must choose between various policies, and for the program, which must link to the automated systems of supplementary carriers so they can cover the appropriate cost-sharing amounts for Medicare claims. MedPAC's June 2002 report will discuss the benefit package design in more detail and present recommendations for its simplification and improvement.

Fiduciary responsibility

The program's fiduciary responsibility to taxpayers and beneficiaries leads to complexity. This responsibility entails ensuring that payments made by the program are legitimate; that is, that they are for medically necessary covered services, provided to eligible beneficiaries by enrolled providers, and for the correct amounts.

Many of providers' concerns about regulatory burden stem from this aspect of the program. Providers view documentation requirements and claims processing issues — including medical review of claims, appeal processes, and potential prosecutions under the False Claims Act — as burdensome or worse.

Is simplification possible? The basic requirement for safeguarding the program's resources must be separated from the mechanisms and regulations used to do it. The basic requirement is intrinsic to the program; the various mechanisms are not, and are ripe for simplification. The goal of being responsible custodians of the trust fund should be examined, however. Should the program aim for zero tolerance of payment errors or for something less? The rhetoric calls for zero tolerance, yet businesses, such as credit card companies, assume some level of loss, enforce what they can but accept that zero is not an efficient outcome, and go about their business. By acting as though zero tolerance is the goal, the Medicare program may limit its options and unnecessarily increase burden on providers and beneficiaries. In fact, although political considerations might make it difficult to enunciate as policy, the program could be simplified by determining a tolerable level of loss.

[1] One possible simplification of the program would be removing the distinction between Part A and Part B services. As discussed, this distinction arose from the legislative history of the program and is in no way intrinsic to providing health care. The distinction complicates administration of the program by having separate contractors and claims processing for Part A and Part B. For example, rural health clinics (RHCs) bill fiscal intermediaries for defined RHC services and carriers for some physician services not included in RHC services. Because there is little coordination between the two, the program may pay twice for the same service if duplicate claims are made (OIG 2001). In carrying out this simplification, issues of financing and eligibility, as well as how to treat beneficiaries who are enrolled in only Part A or Part B, would have to be resolved.

For example, in some situations (such as working beneficiaries with employee heath insurance, or injuries resulting from auto accidents), Medicare is the secondary payer for health care expenses. To ensure that primary insurers are held responsible, Medicare requires that beneficiaries fill out Medicare Secondary Payer (MSP) forms when they seek health care. The problem is that regulations require the form to be filled out each time a beneficiary receives services—even several times in one day. It is unlikely that an 8.5-year-old who has been retired for 20 years will resume employment suddenly during the course of treatment. There appears to be latitude in cases such as this for Medicare to accept some risk by limiting how often and under what circumstances the MSP form must be completed.[2] Such a policy change might save Medicare money as well as decrease burden on beneficiaries and providers.

Beneficiary protection

Because of the vulnerabilities of some Medicare beneficiaries, one of the program's goals is to protect beneficiaries from unscrupulous and incompetent providers, vendors, and plans. Efforts to protect beneficiaries include provider conditions of participation, controls on marketing materials fiom M+C plans, actions to standardize the types of Medigap policies that can be sold, and quality initiatives. Some simplification may be possible in this area. For example, marketing materials for M+C plans are currently reviewed by CMS regional offices, which require that all beneficiaries enrolled in a plan receive the same information. However, some beneficiaries are also members of employee retiree group plans that have additional benefits. If those members receive the same infomiation as others do, they may become confused because they are actually eligible for different benefits. The burden on the beneficiaries could be lessened by sending them the correct information and not the same information that other M+C members receive.

Quality

The quality of care can always be improved and quality problems abound, so it is often tempting for policymakers and regulators to use the Medicare program to force providers and plans to improve quality. The tools to measure and improve quality are new, however, and the federal government has only recently shifted its role fiom one of a guarantor of a minimal level of quality to one in which it increasingly expects plans and providers to continually improve quality.

In this new world, compliance takes on new meaning as regulators begin to use and apply such terminology as process and outcomes measures, demonstrable improvement, statistical relevance, and others that are not easily or neatly defined. One could characterize the world of quality standards compliance as increasingly complex, but there may be ways to create simplicity.

One of the ways that Medicare has made it possible to simplify regulation in the fee-for-service program is through deemed status authority. Deemed status allows organizations accredited by a body with standards and a process deemed to be as stringent as the Medicare requirements to become certified for participation in the program without an additional evaluation from the federal program. Extending this approach to M+C plans could help ease the burden of Medicare-specific requirements for M+C quality improvement.

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[2] CMS is addressing the mare egregious aspects of this regulotion through administrative action. As wiih other examples throughout the text, regulations thct are well known to be burdens ore in many cases being addressed by CMS through administrative actions or by the Congress through legislation, with vcrying degrees of success.

In the fee-for-service program, processes may be simplified by developing perfoimance measures for providers that are useful for organizations and coordinated with private-sector requirements. Many purchasers ask for a higher level of accountability from providers and their efforts need to be aligned with Medicare's. CMS could take the lead in coordinating such efforts.

Simplifying the structure of the program

The structure of the Medicare program—how it is organized to accomplish its varied functions such as enrolling beneficiaries and providers, paying claims, and providing information—is the most promising target for simplification. After reviewing the problems with the current structure, we make four recommendations. The first two relate to removing complexity by instituting a standard nationwide system for claims processing. The last two simplify the enforcement structure.

Problems with the current structure

Providers often ask: "To whom do I go for answers?" "Why do I get audited by three different groups?'' The administration of the Medicare program is oddly divided among many different actors. Just knowing the rules is a challenge for some providers. They can look at written rules in the law; in regulation; in Medicare pronouncements, such as program manuals and operational policy letters; in carrier or intermediary instructions; or on CMS or contractor web pages. They can ask their contractor or CMS questions, but they cannot rely on the answers to protect them if they later become involved in a dispute with the enforcers from the Department of Justice or the HHS OIG.

Providers suffer from incomplete and incorrect information from contractors. In one study, the General Accounting Office (GAO) found that carrier bulletins, which are a principal form of communication between contractors and providers, were often unclear and difficult to use, and in some cases were out of date. Even worse, GAO found that correct and complete answers to questions were received only 15 percent of the time from their sample of carrier telephone call centers. About half the time, answers were incomplete and a third of the time answers were entirely incorrect. Being unable to receive correct information or answers to questions represents a serious burden on providers (GAO 200 1).

Providers operating in areas controlled by several contractors also experience inconsistent interpretation of regulation. For example, claims denials for lab tests vary widely among carriers. Claims for a common lab test were denied 68 percent of the time in one state, but only 7 percent of the time in another, apparently because of differing interpretations of coverage and medical necessity (IOM 2000). For laboratories that provide services to beneficiaries in several states, this variation greatly increases uncertainty and burden.

Some providers have turned to consultants to help them with compliance. But should it be necessary for a provider who wants to follow the rules to have *to* ask for help in doing it? Must the rules be so complex? Cutting out some layers of rules and some regulators would reduce complexity. Medicare does not inherently demand multiple levels of regulators or enforcers, or multiple versions of regulations. For example, carriers are required to write bulletins to providers apprising them of changes in regulations from CMS, but as described above, they do not always provide the correct information in an understandable way, target it to the provider, or produce the bulletins in a timely fashion. Why not eliminate that layer of interpretation and have Medicare speak directly to providers? Other similar steps could be taken to eliminate unnecessary layers that have accumulated over the years.

Beneficiaries have a more basic problem: knowing whom to call. The *Medicare and You 2002* pamphlet has 100 pages of information on the Medicare program; 28 of these are filled with telephone numbers. The office a beneficiary needs to call depends on the beneficiary's location and whether she needs information on Part A, Part B, or from her DMERC or regional home health intermediary (CMS 2001). Woe to beneficiaries who do not know to which part of Medicare their question refers. It may not be apparent to someone receiving care in a RHC to call the fiscal intermediary concerning an office visit. Beneficiaries who go to a different state for care than the one in which they live may also be confused about whom to call for information.

The confusion extends to M+C plans when they must pay Medicare fee-for-service rates to out-of-network providers. This can occur, for example, when plan members seek emergency care away from their usual place of residence. The inconsistent policies of the various contractors make the appropriate rates difficult to determine.

Moving to a nationwide standard system for claims processing

To providers, Medicare is represented by the contractors that process Medicare claims. These contractors deny payment, send checks to providers, and communicate with them on CMS letterhead. They send out bulletins updating Medicare regulations, and what they say is in large measure what providers know of the program. However good or bad CMS is at translating statute to policy and regulation, the ultimate expression of that policy and regulation to the ears and pocketbooks of providers is the contractor's action.

The original legislation for Medicare envisioned a different world than now exists. The program was designed for local administrators to pay locally determined rates for health care services, but because it has evolved to using nationally determined prospective payment systems, Medicare is currently at odds with itself. Local administration and claims payment policies no longer make sense and add unnecessary complexity to the program. They are therefore a prime opportunity for simplification efforts. For a national program that wants to provide equitable treatment to all beneficiaries, moving toward a standard, national claims processing system would be an important step toward simplification.

Currently, claims payment decisions are made by individual contractors that are required to have a local medical review policy (LMRP) when their claims systems make automated denials. LMRPs help contractors identify claims for services that are, for example, inappropriate for a specific diagnosis. These policies frequently differ between contractors; this arbitrary variation would be eliminated under a standard system for claims payment.[3]

[3] LMRPs could be considered essential for the progrom to toke into *account variations* in local medical practice. However, health insurers that operate nationwide do not hove local policies and mony of their clients with employees in differeni locutions would probably object ifthey did. In oddition, same *argue that local* proctice stondords ore giving way to notional stondords. It is also not clear that a state is a small enough area to reflect local medical practices.

Local coverage decisions also may give rise to LMRPs. Some argue that local coverage determinations are needed to allow more rapid introduction of innovations than the national coverage determination process allows.[4] A different approach to coverage detemiination is exemplified by the DMERCs. DMERC LMRPs are jointly developed by the medical directors, but do not have to go through the national coverage determination process and so can be implemented more rapidly. The four DMERCs share one set of LMRPs and therefore claiins are treated the same regardless of what DMERC processes the claim. A similar process could be followed under a standard nationwide claims payment system if there are multiple contractors. Yet another approach would simply be to make the national coverage determination process more responsive using resources formerly used by local contractors.

Others argue that some innovations will not be effective, and demonstrating this locally rather than nationally is good for the program. More broadly, some means of demonstrating the effectiveness of innovations when no national coverage determination has been made may be appropriate. If Medicare were to implement a standard system —using multiple contractors or not—the geographic basis for claims processing might be eliminated. However, the current arrangement of geographically based advisory committees and medical directors could be retained or advisory committees could be established on some other basis, such as type of provider or facility, or tied to the existing national Medicare Coverage Advisory Committee. In any case, medical directors would still need to have authority to make provisional coverage decisions in the absence of national determinations. Doing so in the context of a standard national system however, might allow more deliberate decision making, more explicit consideration of health outcomes, and provide better evidence for national coverage decisions than the current fragmented system.

If the goal is a nationwide Medicare program in which all beneficiaries and providers are treated consistently, then having 100 or more private sector contractors interpreting and implementing the program is not a good idea. At the same time, the mechanism for paying and selecting contractors is not aimed at efficiency or perfomiance. Because contractors are paid their costs, they have no incentive for increasing their efficiency. Because many of them operate under no-competition clauses, they have no great incentive for customer-pleasing performance. The fact that some contractors do their work efficiently and please their customers speaks highly of those contractors and their public spirit, but should not be the basis for perpetuating the current system.

Current efforts to change the rules under which CMS selects and pays contractors are a step in the right direction, but why continue the system at all? We have shown that its existence is a result of how Medicare began and that the conditions that may have justified it at the time (such as payment based on costs and use of local UCR rates) no longer exist. In addition, even under the current system, it is clear that contractors do not have to be local. Noridian Government Services is the Part B carrier for Alaska, Arizona, Colorado, Hawaii, Iowa, Nevada, North Dakota, Oregon, South Dakota, Washington, and Wyoming. The carrier for Washington D.C. is in Texas and is owned by a firm in South Carolina. One contractor in South Carolina handles DME supplier enrollment for the entire nation, a function that includes conducting site visits nationwide. Why continue having multiple "locally based" contractors if they contribute to complexity and burden?

[4] For a local coverage determination, the contractor medical director must decide whether the device or procedure is a covered benefit under Medicare, assure that it is not statutorily excluded, and determine that it is safe and effective. The medical director must then give guidance to providers on reasonable and necesrory use and explain haw to submit claims (either by assigning a temporary code or directing that it be billed under an existing code). The notional coverage determination process is considered to require a higher level of evidence, toke more time, and be more cumbersome.

CMS should move to a standard nationwide system of claims processing and eliminate local descriptions of policy and regulation. The Congress should allow CMS to contract as necessary to implement a standard system efficiently.

Moving to a standard nationwide system of claims processing and eliminating local descriptions of policy and regulation would make it possible to have one accepted statement of Medicare policy, help ensure consistent descriptions and understanding of regulations, and allow the development of standard instructional materials. The current complexity, inconsistency, and uncertainty in the program would be reduced, along with the associated burden on providers and beneficiaries.

The Congress would have to eliminate current contracting limitations and CMS would have to determine the most efficient division of labor between govemnient and contractors, as well as the optimum number of contractors for claims processing (including the common working file operation), provider education, and program safeguard activities. The current division of labor and contractor operations should be rethought and simplified to give providers and beneficiaries a consistent source of information and consistent results of claims adjudication. This recommendation represents a significant change of direction for the program and will be difficult to accomplish. Providers should be consulted on Medicare operations and coverage policies and their suggestions used to improve the system. The existing carrier advisory committees could be reconfigured for this role, or another mechanism could be used.

Moving to a standard nationwide system may require more resources for CMS, particularly for fielding more up-to-date automated systems. Consolidating niultiple automated systems has proven to be a difficult task in the past for Medicare and private sector organizations and carries significant **risk.** It will undoubtedly prove challenging in this case as well and, therefore, sufficient time **and** resources, human and other will have to be made available for planning and execution. Increased resources for CMS, as endorsed in the past by MedPAC, may pay large dividends in better information for providers and in more responsive and capable infomiation handling (MedPAC 1999). These investments, in turn, could pay off not only with more responsive claims processing but also with an enhanced capability to identify discrepant behavior for enforcement actions. CMS should have the authority to redirect resources made available through eliminating inefficient, duplicative policy development in the current contractor system.

The above recommendation would be an iniportant step to help providers and beneficiaries get more consistent and correct answers to their questions. The commission also recommends the following as a next step.

The Medicare program should provide timely, binding written guidance to plans and providers. Plans and providers that rely on such guidance should not be subject to civil or criminal penalties or be required to refund related payments if that guidance is later found to be in error.

A serious complaint of providers is that they can get answers from contractors, file claims accordingly, receive payment and then retrospectively be told that their actions were incorrect and sometimes actionable. If some layers of the present system were cut out, the likelihood of correct, timely information being communicated would increase. It might then be possible to assure providers who make a good faith effort to do the right thing and receive affirmative official guidance that they will not be held liable for penalties or required to refund related payments if the guidance is later found to be incorrect.[5] In order for guidance to be timely, the possibility of considering e-mail as a form of written guidance should be examined.

Incorrect guidance under the present system can be caused by differences between information in the contractors' automated systems and that in regulation. To meet tight deadlines, programming changes are often made before regulations are finalized. Such changes made to the automated systems are reality for contractors and providers. If providers do what the contractors' systems tell them to do, then the OIG can later say that providers were wrong, even if contractors encouraged them to behave as they did. Having a single standard automated system would help simplify the process of moving from regulation to implementation.

As contractor roles are rationalized and some of the layers removed, the role of the CMS regional offices and the consortium structure in contractor management might be reconsidered.[6] If the contractor structure were rationalized and did not retain a local or regional basis, the current regionally oriented management structure should change as well.

Other functions of the regional offices might also change. For example, their role in supervising M+C plans may need to be revisited if the review of marketing materials is revised. The role of CMS regional offices with respect to beneficiaries may also be reexamined. Regional offices have limited contact with beneficiaries, as evidenced by the fact that they do not have toll-free telephone numbers for beneficiaries and are not included in the list of offices under *Where do I call for help with my Medicare questions?* in the *Medicare and You* pamphlet. Some observers have recommended that a local CMS presence be created within local Social Security offices so that beneficiaries can have someone in their immediate area to answer their questions (Vladeck and Cooper 2001). How those local representatives would coordinate with regional offices, or if they would report directly to the central office, must be determined.

Simplifying enforcement

A highly visible face of Medicare to providers—one they do not want to see—consists of the enforcers: the OIG in HHS and the various arms of the Department of Justice (DOJ), the Federal Bureau of Investigation (FBI) and the U.S. Attorney's offices. Fear of unfounded prosecution and the formidable array of enforcement tools available has reportedly created a pall over the program among providers. It is clear from the explosive growth in the compliance industry that this fear is palpable and real.

[5] We use the term "official guidance" to mean written rotherthan oral direction from the program. The courts hove never held verbal guidance to be binding an the government. Moreover, if guidance were not written, there would be no reasonable way to track such exchanges. This recommendation would require CMS to create a process for providers, suppliers and beneficiaries to request and receive sanctioned written guidance on program questions.

[6] The 10 CMS regions ore divided into 4 consortia for contract management purposes. Regionol offices also play a major role in Medicaid and State Children's Health Insurance Progrom administration, oversee state survey agencies ond the peer review organizations, and perform other functions.

It is good if providers and suppliers contemplating fraudulent activity fear detection and prosecution. The problem is when providers trying to do the right thing are discouraged from appropriate behavior or even from participating in the program. Writing rules and enforcement policies for the "bad apples" may cause a serious misallocation of resources and unnecessarily complicate things for the vast majority of honest providers.

[redacted]

CMS should explore ways to reduce routine administrative requirements for plans and providers that demonstrate sustained good performance.

One approach to solving the problem of burden is to scrutinize providers and plans less as they prove themselves reliable. Doing so would create incentives for good behavior, lessen burden on compliant providers, and free resources to pursue less-than-compliant providers. For example, examination of M+C plan networks could occur less frequently for plans that repeatedly demonstrated the requisite network availability and quality, and physicians with sustained good performance could be excused from resubmitting management data every time office personnel change. Private-sector models should be investigated as CMS evaluates strategies to reward good performance.

Another problem in enforcement is that many poorly coordinated entities are involved in setting, interpreting, and enforcing rules. Rationalization of the contractor structure may help to some extent. Also, legislation already has been proposed to address some of the most burdensome regulations identified by providers. However, beyond changing individual regulations, the agencies involved might attempt to rationalize the enforcement process itself, for example, by ensuring that audits are non-duplicative. Because the enforcement agencies have grown rapidly with the increased funding for their fraud and abuse activities, their roles may not be optimal for the current environment.[7]

[redacted]

The Secretary of Health and Human Services should work with the Department of Justice to improve consistency and eliminate redundancy in enforcement roles and activities.

The Health Insurance Portability and Accountability Act of 1996 expanded the duties of the OIG to include coordination of federal, state and local enforcement efforts targeting health care fraud. Under HIPAA's health care fraud and abuse program, the DOJ also received new investigative powers and additional funding to support its responsibilities through the FBI and U.S. Attorneys' offices. Although the Secretary of HHS and DOJ issued joint guidelines to carry out fraud and abuse activities following passage of HIPAA, reviewing how those guidelines are implemented among the OIG, FBI and U.S. Attorneys' field offices may yield opportunities for better leadership and coordination, particularly to reduce the incidence of providers being audited by multiple entities during an investigation. Rationalizing resources to emphasize provider education and improve communication to avoid government waste can be accomplished administratively, but statutory changes would be required to transfer or consolidate which executive branch agency could levy penalties. exclude providers, and prosecute civil or criminal penalties.

[7] *In fiscal year 2000,* HHS OIG had more than 1,000 full-time equivalent (FTE) staff devoted to Medicare and Medicaid investigations. Department of Justice had more than 1,200 FTE staff involved in health care fraud control activities (GAO 2001b). In comparison, CMS has approximately 4,200 FTE staff.

Moderating the pace of change

A significant source of complexity is the pace of change in Medicare regulations. Constant change will complicate any system because each new regulation must be developed and will interact in possibly unanticipated ways with previous requirements. New regulations also must be promulgated to the affected community, which entails an educational effoi-t. According to many providers, keeping up with changes in regulation is one of the most difficult and burdensome aspects of participating in the Medicare program. It also creates a burden on the regulators and policymakers themselves, as was perhaps best illustrated by the BBA of 1997, which required that HCFA develop four new prospective payment systems[8] and numerous other changes at a time when it was already overloaded with trying to cope with a major reorganization and planning for Y2K.

Plans and providers are concerned that the rules of the game keep changing, making Medicare an unpredictable, and thus undesirable, business partner. M+C plans, for example, have seen major changes in the payment mechanism almost every year since 1997, making it very difficult to make long-range business plans and possibly discouraging market entry.

Ironically, one aspect of the problem stems from the Congress being so responsive to provider concerns about Medicare. If the Congress were less prescriptive in its legislation and gave CMS more leeway in implementation and timing, it might protect plans, providers and beneficiaries better. For example, the implementation date for Medicare legislation could be left open in statute, but be coupled with a requirement that CMS produce a regulatory calendar showing planned implementation dates. This would create an opportunity for some planning and public discussion about the interaction among various items on the agenda. If the Congress had severe objections, it could override CMS.

Another way to moderate change would be to have CMS test regulations before putting them in effect. The recent development and implementation of several PPSs called for in the BBA shows why this might be desirable. A poorly conceived system inflicted on an entire industry can have many negative effects, including incentives for behavior that increases Medicare's cost. In addition, poorly conceived systems will create demand for Congressional action, which can result in more prescriptive law and further changes in regulation.

The Congress should provide reasonable time lines and resources for CMS to develop and test regulations thoroughly before implementation.

When appropriate, CMS should test regulations that increase complexity and burden before putting them into effect for an entire industry. For the testing to be credible, the testers should be independent of those proposing the manner of regulation and sufficient sites should be chosen to illustrate any differential impacts of the proposed regulation. Time should be allowed for proper development and consultation with industry so that the likely impact of regulations can be understood as soon as possible. CMS should investigate whether this consultation can be accomplished within the strictures of the APA and the FACA, or whether some aspects of developing Medicare regulations could be exempt from those laws.

[8] For home health services and care in skilled nursing facilities, rehabilitation hospitals, and hospital outpatient departments.

Simplifying program operations

The continuing move to prospective payment in Medicare creates complexity and challenges for the program to make accurate payments. However, this evolution should not necessarily burden providers. The data collection burden might also be lessened.

Data collection

Some of the data collected by CMS may no longer be needed because the program has changed. For example, hospital cost reports were designed to permit cost-based payment to hospitals; as a result, they contain a great deal of data. Some simplification may be possible now that hospitals are paid primarily through PPS. As another example, adjusted community rate proposals (ACRPs) are detailed submissions required of all M+C plans. The ACRP formula adjusts the costs of caring for commercial plan members to estimate the higher costs of caring for Medicare members. Before the BBA, at least 50 percent of the enrollment in M+C plans had to be commercial members; now, Medicare no longer requires plans to have commercial members, and therefore basing estimates on the cost of commercial members is no longer logical.[9]

In some cases, data collection requirements may have been excessive from the start. For example, when HCFA designed the prospective payment system for skilled nursing facilities (SNFs), the agency adopted an existing care-planning tool—the Minimum Data Set (MDS)—as its patient assessment instrument. However, increases in assessment frequency and the decision not to trim the original instrument led to excessive data requirements. Originally, SNF staff were required to fill out the MDS at 90-day intervals. Under PPS, the frequency increased; patients are now assessed on days 5, 14, 30, 60, 90, and when a significant change in condition occurs. While the original MDS was administered chiefly to long-term patients, under PPS it also applied to patients who stay for much shorter periods and to all types of patients, including Medicare, Medicaid and private sector.[10] Out of the 350+ items, only 109 are used to adjust per diem rates under the SNF PPS. Twenty-four items are used as quality indicators. Many items do not have an explicit rationale. Limiting the data requirement would remove a significant burden from SNF operators.

Regulation "sunset"

Outdated data collection requirements illustrate a larger point. As the program changes, some regulations, manuals, instructions, and other issuances become outdated and should be eliminated or simplified. CMS should expand its efforts to eliminate obsolete regulations and develop a sunset mechanism triggered by program changes that would allow for the identification and elimination of all regulations, manuals, instructions and other issuances that were made obsolete by the change.

[9] Some argue that ACRPs are not needed anyway because their primary function is to ensure thot plans return payments above their revenue requirements to beneficiaries in the farm of additional benefits and that function is petforrned by the market. In areas with multiple plans, additional benefits will be offered by efficient plans as a marketing tool. If they do not offer reasonable additional benefits, members will leave and enroll in plans that do. Even if only one plan operates in an area, beneficiaries will not join unless value is added.

[10] The Medicare program can dictate data collection far nan-Medicare patients if Medicare participation implies Medicore's approval of the provider. The rationale appears to be thot if Medicare agrees to use a facility far Medicare beneficiaries it is giving it a quality seal of appravol, an which other patients might rely.

CMS should eliminate regulations and other issuances that become obsolete as a result of program changes.

For example, as new PPSs are implemented, an effort should be made to eliminate regulations that supported previous payment mechanisms and are now obsolete. The ACRP process, which was predicated on commercial enrollment in plans that provide services to Medicare enrollees, should have been eliminated when the BBA eliminated the requirement for commercial enrollment. After CMS identifies obsolete requirements, Congress may have to take legislative action to eliminate them if the requirements are specifically called for in law.

Payment

As the Medicare Payment Advisory Commission, we are particularly sensitive to the complexity of Medicare payment systems, both within individual payment systems and between different payment systems.

Within individual PPSs, payment accuracy depends on the unit of payment, the product classification system, relative values, adjustments to payment rates, and base payments. As the quest for accuracy of payment continues, more refmements are added to the system. For example, the PPS for hospital inpatient care is based on diagnosis related groups (DRGs). Because some providers began to transfer patients to post-acute settings earlier to decrease their inpatient costs, certain DRGs were designated as transfer DRGs and payments for those DRGs were lowered when patients were transferred to other settings earlier than usual. Such refinements increase the complexity of the payment system.

At the same time, the Congress often legislates exceptions to a system to protect certain providers. Within the inpatient hospital category, for example, rural hospitals receive special payments if they are designated as rural referral hospitals, Medicare-dependent hospitals, sole community hospitals, or critical access hospitals. Each of these designations has specific criteria and may fulfill certain goals for the program. Nonetheless, the designations make the program more complex. Medicare must regulate for every exception (not just those relating to payment) and the program would be simpler with fewer exceptions.

The differences in payment systems among settings increases overall complexity and may lead to conflicting incentives and unforseen outcomes. To some extent, Medicare payments depend on the name over the door as well as on the activities inside. For example, a physician may perform the same procedure in a hospital outpatient department, an ambulatory surgical center, and a doctor's office, but payment will differ by setting. This particular source of complexity—the definition of many types of settings, each with its own payment system—may be peculiar to Medicare, and private-sector approaches may guide simplification.

More generally, the boundaries—geographic, definitional, or professional—may make payments more accurate, but they also introduce complexity to the payment system and raise the possibility of providers shifting over boundaries to increase payment. For example, a physician in a rural area might choose to have an office or to be redefined as an RHC because payment differs between these two settings. This creates an opportunity for the physician, but it is also a burden. The physician must determine what definition would be preferable, taking into account any additional requirements for an RHC, how payments will differ, and any effect on his *or* herpatients, such as changes in cost sharing.

The ideal simplification for payment would be to remove some of the boundaries or improve accuracy in ways that do not complicate the program. Failing that, improved technology may help relieve the burden of the payment system, if not its complexity. It might be possible to make much of the payment system's intricacy transparent to providers.

Using technology to simplify the program

Efforts to simplify the Medicare program and relieve the burden of Medicare regulations must take advantage of new technology that could modernize program administration.

internet for communication

Having the Intemet commonly available could improve communication between the Medicare program and both beneficiaries and providers. Building on earlier recommendations to remove layering, the Internet makes possible direct communication between CMS and both beneficiaries and providers. In addition to easier and more accurate dissemination of information, it should be possible for providers to determine whether claims will be acceptable before actual submittal. (All the automated edits for single claims could be made available to providers so that only clean claims are submitted.) For example, if information such as a beneficiary number were missing or incorrect, the provider could find out immediately and correct the claim. If two procedures were submitted on the same claim that were not allowed together, the provider would know immediately. Given one standard claims processing system, CMS could make such a pre-submission service available over the Internet or even on CD-ROM. Just as tax preparation software creates a simple interface with the extremely complex tax system, a better interface could remove some of the burden of the complex Medicare system.

Health Insurance Portability and Accountability Act of 1996 standardization

Although the advent of HIPAA regulations is enormously complicated, the standardization of billing forms may lead to simplification and lessen burden. Once a standard form is defined. promulgated, and put into practice, the burden of billing Medicare should decrease. Legislation delaying the implementation of the HIPAA transaction standards is in process.

Electronic medical records

The eventual ready availability and use of electronic medical records could relieve some of the burden of Medicare audits and medical record review, and possibly of documentation for evaluation and management visits. Care for beneficiaries might also improve: Medicare's efforts to monitor quality through an episode of care when beneficiaries are treated by multiple providers in a variety of settings could be greatly enhanced by access to a comprehensive electronic medical record.

The Congress should appropriate the necessary resources for CMS to acquire new technology that would simplify administrative processes and improve information exchange with program participants.

In many ways, Medicare will remain an extremely complex program because much of its complexity is irreducible. However, the complexity that stems from difficulties in information sharing and from complicated payment rules may be made less of a burden on providers through judicious application of more modern information systems. Developing better systems is a long-term opportunity that CMS should be given the appropriate resources to take. ■

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APPENDIX A

Layers of regulatory issuances

APPENDIX A

Layers of regulatory issuances

Table A-1 attempts to capture the complexity added to the Medicare program by the large volume of guidance documents issued. The chart merely documents those issuances made during calendar year (CY) 2000. It does not list the documents in existence or issuances made prior to that time period. For example, the two relevant volumes of the Code of Federal Regulations are not listed, though CY 00 Federal Register (FR) issuances of regulations are listed. Providers and suppliers are, thus, required to be in compliance with all existing guidance materials and to keep abreast of the many changes imposed by new issuances.

In addition, Table A-1 lists most of the standard documents issued by the relevant government entities. It does not, however, capture every document issued that contained relevant policy guidance. For example, the Centers for Medicare & Medicaid Services (CMS) issues "Q & A" documents, posing and responding to questions on various topics. These are not, however, issued with any regularity, nor are they easily accessible as a distinct group of documents; thus, they have not been included.

TABLE A-1

Medicare-relevant issuances during calendar year 2000

Regulator	Issuance/publication	Number	Sample documents
Congress	Laws	1	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554)
Department of Health and Human Services (DHHS)	Regulations	9	Organ Procurement and Transplantation Network, final rule (65 FR 15252
	Information collection requests	5	Office for Civil Rights standardized automated review format far the conduct of civil rights compliance investigations of health care providers who have requested certification to participate in the Medicare Program (65 FR 25925)
	Notices	12	Notice of interest rate an overdue debts (65 FR 25730)
	Other	46	Notice of meeting of the Advisory Committee on Blood Safety and Availability (65 FR 14283)
DHHS/Centers for Medicare & Medicaid Services	Regulations (published in FR)	41 issuances	• Prospective payment system far home health agencies, final rule (65 FR 41127-41214) • Requirements far the recredentialing of Medicare+Choice organization providers, proposed rule (65 FR 81813-81815)
	Proposed Information Collection Requests' (published in FR)	165	Follow-up of Medicare+Choice disenrollees receiving fee-for-service inpatient hospital care, Form No HCFA-10017 (65 FR 65860)
	Notices (published in FR)	30	Hospice wage index (65 FR 600071-600820)
	Other (published in FR)	A6	Notice of meeting of the Negotiated Rulemaking Committee an the Ambulance Fee Schedule (65 FR 4545)
	23 manuals	133 revisions	• Intermediary Manual Transmittal No. 1811, 10/00, adding new section providing coverage, billing, and payment instructions for edrocorpareal imrnunoadsarption using Protein A columns • Skilled Nusing Facility Manual Transmittal No. 364, 5/00, manualizing policies in May 1996 regional office memorandum on the prohibition of two or more distinct part skilled nursing facilities in o single institution
	Program memoranda	102	Program Memorandum PMI A-00-94 new end-stage renal disease (ESRD) composite payment rates effective January 1,2001
	Operational policy letters (OPLs)	16	OPL #11A, 1/17/00, reporting appeal and quality of care grievance aggregate data to beneficiaries upon request
	Administator decisions	58	Tri-State Memorial Hospitol v. Blue Crass and Blue Shield Association, HCFA administrator decision, (May 8, 2000) ESRD exception request
	Provider Reimbursement Review Board (PRRB) decisions	81	Lloyd Noland Hospital (Fairfield, Ala.) v. Blue Cross and Blue Shield Association/Blue Cross and Blue Shield of Alabama, PRRB Hearing (April 5, 2000) PRRB Heoring Dec. No. 2000-D43, reasonable compensation equivalent limits
DHHS/Center for Medicare and Medicaid Services	Medicare Geographic Classification Review Board (MGCRB) decisions	10	MGCRB 10/6/00 00C0586 Bruce A. Tedesco & Ca., Inc
	Departmental Appeals Board decisions	56	Garden City Medical Clinic v. Health Care Financing Adminitration, HHS Deparmtnetal Appeals Board, Civil Remedies Division (September 11, 2000). Doc. No C-99-766, Dec. No. CR 698. conditions of participation
DHHS/Office of the inspector General (OIG)	Regulations (published in FR)	A	Fraud and abuse; revised OIG civil money penalties resulting from Public Law 104-191, final rule (65 FR 24400)
	Compliance guidance	7	OIG compliance program for individual and small group physician practices (65 FR 59434)
	Program exclusions	12	Notice of program exclusions. August 2000 (65 FR 57358)

Note ' Filed with the Office of Informotion and Regulatory Affairs of the Office of Management and Budget pursuant to the Paperwork Reduction Act, 44 §33501-3520

FR (Federal Register)

Source MedPAC review of Congressional ond DHHS issuances

APPENDIX B

Commissioners' voting on recommendations

Commissioners' voting on recommendations

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), the Congress required MedPAC to call for individual Commissioner votes on each recommendation, and to document the voting record in its report. The information below satisfies that mandate.

Recommendation 1

CMS should move to a standard nationwide system of claims processing and eliminate local descriptions of policy and regulation. The Congress should allow CMS to contract as necessary to implement a standard system efficiently.

Yes:	*Braun, Burke, Feezor, Hackbarth, Loop, Muller, Nelson, Newhouse, Newport, Raphael, Reischauer, Rowe, Stowei-s*
No :	*DeBusk*
Not Voting:	*Rosenblatt*
Absent:	*Smith, Wakefield*

Recommendation 2

The Medicare program should provide timely, binding written guidance to plans and providers. Plans and providers that rely on such guidance should not be subject to civil or criminal penalties or be required to refund related payments if that guidance is later found to be in error.

Yes:	*Braun, Burke, Feezor, Hackbarth, Muller, Nelson, Newhouse, Newport, Raphael, Reischauer; Rosenblatt, Rowe, Stowers, Wakefield*
Absent:	*DeBusk, Loop, Smith*

Recommendation 3

CMS should explore ways to reduce routine administrative requirements for plans and providers that demonstrate sustained good performance.

Yes:	*Braun, Burke, Feezoi; Hackbarth, Loop, Muller, Nelson, Newhouse, Newport, Raphael, Reischauer; Rosenblatt. Smith, Stowei-s, Wakefield*
Absent:	*DeBusk, Rowe*

Recommendation 4

The Secretary of Health and Human Services should work with the Department of Justice to improve consistency and eliminate redundancy in enforcement roles and activities.

Yes:	*Braun, Burke, Feezoi; Hackbarth, Loop, Muller, Newhouse, Newport, Reischauer; Rosenblatt, Rowe, Stowers*
Absent:	*DeBusk, Nelson, Raphael, Smith, Wakefield*

continued on next page

Commissioners' voting on recommendations (continued)

Recommendation 5

The Congress should provide reasonable time lines and resources for CMS to develop and test regulations thoroughly before implementation.

Yes: *Braun, Burke, Feezor; Hackbarth, Loop, Muller, Nelson, Newhouse, Newport, Reischauei; Rosenblatt, Rowe, Stowers*
Absent: *DeBusk, Raphael, Smith, Wakefield*

Recommendation 6

CMS should eliminate regulations and other issuances that become obsolete as a result ofprogram changes.

Yes: *Braun, Burke, DeBusk, Feezor; Hackbarth, Loop, Muller, Nelson, Newhouse, Newport, Raphael, Reischauer; Rosenblatt, Rowe, Stowers*
Absent: *Smith, Wakefield*

Recommendation 7

The Congress should appropriate the necessary resources for CMS to acquire new technology that would simplify administrativeprocesses and improve infomiation exchange with program participants.

Yes: *Braun, Buske, DeBusk, Feezor; Hackbarth, Loop, Muller, Nelson, Newhouse, Newport, Raphael, Reischauer, Rosenblatt, Rowe, Stowers*
Absent: *Smith, Wakefield*

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Testimony

Before the Special Committee on Aging, U.S Senate

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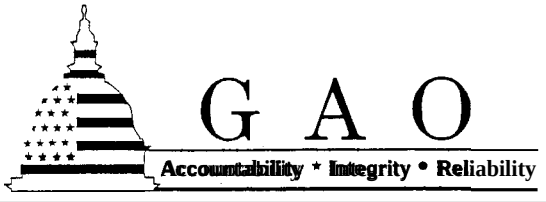
MEDICARE MANAGEMENT

CMS Faces Challenges in Safeguarding Payments While Addressing Provider Needs

Statement of Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues



Mr. Chairman and Members of the Committee:

We are pleased to be here today as you discuss the administration of the Medicare program and activities undertaken to safeguard the Medicare trust fund. In fiscal year 2000, Medicare made payments of over $220 billion to hundreds of thousands of providers who delivered services to nearly 40 million beneficiaries. Because of Medicare's vast size and complex structure, in 1990 we designated it as a high-risk program—that is, at risk of considerable losses to waste, fraud, abuse, and mismanagement—and it remains so today. Since that time, we have consistently reported on the efforts of the Health Care Financing Administration (HCFA), recently renamed the Centers for Medicare and Medicaid Services (CMS),[1] to safeguard Medicare payments and streamline operations.

Each year improper payments cost Medicare billions of dollars. Therefore, the process of enforcing program payment rules is critical to the viability of the program. My remarks today will focus on the importance of performing activities to protect the integrity of Medicare, while striking a balance of simplicity and responsiveness to the providers that bill the program. My comments are based on our previous and ongoing work and published reports by others.

In brief, at the heart of effectively administering Medicare is CMS' responsibility for protecting the integrity of the program while, at the same time, ensuring that providers are treated fairly. CMS relies on its claims administration contractors to administer Medicare and interact with all of its stakeholders—including providers. As CMS' contractors and others have become more aggressive in identifying and pursuing inappropriate payments, providers have expressed concern that Medicare has become too complex and difficult to navigate. Although CMS monitors the effectiveness of contractors' program management and safeguard activities, the agency's oversight of its contractors has historically been weak. In the last 2 years, however, the agency has made substantial progress. Our ongoing work has identified several areas in which CMS still needs improvement—especially in ensuring that contractors are providing accurate, complete, and timely information to providers about Medicare billing rules and coverage policies.

[1] Our statement will continue to refer to HCFA where our findings apply to the organizational structure and operations associated with that name.

Background

The complexity of the environment in which CMS and its contractors operate the Medicare program cannot be overstated. CMS is an agency within the Department of Health and Human Services (HHS) but has responsibilities over expenditures that are larger than those of most other federal departments.[2] Under the fee-for-service system—which accounts for over 80 percent of program beneficiaries—physicians, hospitals, and other providers submit claims for services they provide to Medicare beneficiaries to receive reimbursement. The providers billing Medicare, whose interests vary widely, create with program beneficiaries and taxpayers a vast universe of stakeholders.

About 50 Medicare claims administration contractors[3] carry out the day-to-day operations of the program and are responsible not only for paying claims but for providing information and education to providers and beneficiaries that participate in Medicare. They periodically issue bulletins that outline changes in national and local Medicare policy, inform providers of billing system changes, and address frequently asked questions. To enhance communications with providers, the agency recently required contractors to maintain toll-free telephone lines to respond to provider inquiries. It also directed them to develop Internet sites to address, among other things, frequently asked questions. In addition, CMS is responsible for monitoring the claims administration contractors to ensure that they appropriately perform their claims processing duties and protect Medicare from fraud and abuse.

In 1996, the Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), in part to provide better stewardship of the program.[4] This act gave HCFA the authority to contract with specialized entities, known as program safeguard contractors (PSC), to combat fraud, waste, and abuse. HCFA initially selected 12 firms to conduct a variety of program safeguard tasks, such as medical reviews of claims and audits of providers' cost reports. Previously, only claims administration contractors performed these activities.

'Medicare ranks second only to Social Security in federal expenditures for a single program.

[3]Contractors that process and pay part A claims (i.e. for inpatient hospital, skilled nursing facility, hospice care, and certain home health services) are known as fiscal intermediaries. Contractors paying and processing part B claims (i.e. for physician, outpatient hospital services, laboratory and other services) are known as carriers.

[4]P.L. 104-191.

Inappropriate Payments Underscore The Importance of Integrity Efforts, Raising Provider Concerns

In response to the escalation of improper Medicare payments, Congress and executive branch agencies have focused attention on efforts to safeguard the Medicare Trust Fund. HIPAA earmarked increased funds for the prevention and detection of health care fraud and abuse and increased sanctions for abusive providers. The HHS Office of Inspector General (OIG) and the Department of Justice (DOJ) subsequently became more aggressive in pursuing abusive providers. In response, the medical community has expressed concern about the complexity of the program and the fairness of certain program safeguard activities, such as detailed reviews of claims, and the process for appealing denied claims. Recent actions address some of these concerns.

Program Integrity Efforts Have Intensified in Response to Improper Payments

Since 1996, the HHS OIG has repeatedly estimated that Medicare contractors inappropriately paid claims worth billions of dollars annually. The depletion of Medicare's hospital trust fund and the projected growth in Medicare's share of the federal budget have focused attention on program safeguards to prevent and detect health care fraud and abuse. It has also reinforced the importance of having CMS and its contractors develop and implement effective strategies to prevent and detect improper payments.

HIPAA provided the opportunity for HCFA to enhance its program integrity efforts by creating the Medicare Integrity Program (MIP). MIP gave the agency a stable source of funding for its safeguard activities. Beginning in 1997, funding for antifraud-and-abuse activities has increased significantly—by 2003, funding for these activities will have grown about 80 percent. In fiscal year 2000, HCFA used its $630 million in MIP funding to support a wide range of efforts, including audits of provider and managed care organizations and targeted medical review of claims. By concentrating attention on specific provider types or benefits where program dollars are most at risk, HCFA has taken a cost-effective approach to idenbfy overpayments. Based on the agency's estimates, MIP saved the Medicare program more than $16 for each dollar spent in fiscal year 2000.

CMS is only one of several entities responsible for ensuring the integrity of the Medicare program. HIPAA also provided additional resources to both the HHS OIG and DOJ. The HHS OIG has emphasized the importance of safeguarding Medicare by auditing providers and issuing compliance guidance for various types of providers. It also pursues potential fraud brought to its attention by contractors and other sources, such as beneficiaries and whistleblowers. DOJ has placed a high priority on

identifying patterns of improper billing by Medicare providers. DOJ investigates cases that have been referred by the HHS OIG and others to determine if health care providers have engaged in fraudulent activity, and it pursues civil actions or criminal prosecutions, as appropriate.[5] The False Claims Act (31 U.S.C. sec. 3729 to 3733) gives DOJ a powerful enforcement tool as it provides for substantial damages and penalties against providers who knowingly submit false or fraudulent bills to Medicare, Medicaid, or other federal health programs. DOJ has instituted a series of investigations known as national initiatives, which involve examinations of similarly situated providers who may have engaged in common patterns of improper Medicare billing.

Provider Concerns Grow With the Expansion of Safeguard and Enforcement Activities

As safeguard and enforcement actions have increased, so have provider concerns about their interaction with contractors. Individual physicians and representatives of medical associations have made a number of serious charges regarding the following.

- **Inadequate communications from CMS' contractors.** Providers assert that the information they receive is poorly organized, difficult to understand, and not always communicated promptly. As a result, providers are concerned that they may inadvertently violate Medicare billing rules.
- **Inappropriate targeting of claims for review and excessive paperwork demands of the medical review process.'** For example, some physicians have complained that the documentation required by some contractors goes beyond what is outlined in agency guidance or what is needed to demonstrate medical necessity.
- **Unfair method used to calculate Medicare overpayments.** Providers expressed concern that repayment amounts calculated through the use of samples that are not statistically representative do not accurately represent actual overpayments.
- **Overzealous enforcement activities by other federal agencies.** For example, providers have charged that DOJ has been overly aggressive in its use of the False Claims Act and has been too accommodating to the

[5] In fiscal year 2000, DOJ filed 233 civil cases and reported recoveries of over $840 million related to civil health care fraud.

[6] Contractors conduct medical reviews—either prior to or after payment—to identify claims that should not be or should not have been **paid** because services are not covered or are not medically necessary.

OIG's insistence on including corporate integrity agreements in provider settlements.[7]

- **Lengthy process to appeal denied claim.** Related to this issue is that a provider who successfully appeals a claim that was initially denied does not earn interest for the period during which the administrative appeal was pendmg.

We have studies underway to examine the regulatory environment in which Medicare providers operate. At the request of the House Committee on the Budget and the House Ways and Means Subcommittee on Health, we are reviewing CMS' communications with providers and have confirmed some provider concerns. For example, our review of several information sources, such as bulletins, telephone call centers, and Internet sites, found a disappointing performance record. Specifically, we reviewed recently issued contractor bulletins — newsletters from carriers to physicians outlining changes in national and local Medicare policy — from 10 carriers. Some of these bulletins contained lengthy discussions with overly technical and legalistic language that providers may find difficult to understand. These bulletins also omitted some important information about mandatory billing procedures. Similarly, we found that the calls we placed to telephone call centers this spring were rarely answered appropriately. For example, for 85 percent of our calls, the answers that call center representatives provided were either incomplete or inaccurate. Finally, we recently reviewed 10 Internet sites, which CMS requires carriers to maintain. We found that these sites rarely met all CMS requirements and often lacked user-friendly features such as site maps and search functions. We are continuing our work and formulating recommendations that should help CMS and its contractors improve their communications with providers.

We are also in the preliminary stages of examining how claims are reviewed and how overpayments are detected to assess the actions of contractors as they perform their program safeguard activities. Although we have not yet formulated our conclusions, agency actions may address some provider concerns. For example, HCFA clarified the conditions under which contractors should conduct medical reviews of providers. In August 2000, the agency issued guidance to contractors regarding the

[7] A corporate integrity agreement is an obligation imposed on a provider by the HHS OIG as part of a settlement of a potential fraud matter. It requires the provider to improve compliance and to report periodically to the OIG.

selection of providers for medical reviews, noting, among other things, that a provider's claims should only be reviewed when data suggest a pattern of billing problems. Although providers may be wary of the prospect of medical reviews, the extent to which they are subjected to such reviews is largely unknown. Last year, HCFA conducted a one-time limited survey of contractors to determine the number of physicians subject to complex medical reviews in fiscal year 2000. It found that only 1,891, or 0.3 percent, of all physicians who billed the Medicare program that year were selected for complex medical reviews-examinations by clinically trained staff of medical records.'

In regard to physician complaints about sampling methodologies, HCFA outlined procedures to give providers several options to determine overpayment amounts. Contractors would initially review a small sample (probe sample) of a provider's claims and determine the amount of the overpayment.[9] A provider could then (1) enter into a consent settlement, whereby the provider accepts the results of this probe review and agrees to an extrapolated "potential" overpayment amount based on the small sample, (2) accept the settlement but submit additional documentation on specific claims in the probe sample to potentially adjust downward the amount of the projected overpayment, or (3) require the contractor to review a larger statistically valid random sample of claims to extrapolate the overpayment amount. According to agency officials, although providers can select any of these options, consent settlements are usually chosen when offered because they are less burdensome for providers, as fewer claims have to be documented and reviewed.

In response to concerns regarding its use of the False Claims Act, DOJ issued guidance in June 1998 to all of its attorneys that emphasized the fair and responsible use of the act in civil health care matters, including national initiatives. In 1999, we reviewed DOJ's compliance with its False Claims Act guidance and found that implementation of this guidance varied among U.S. Attorneys' Offices." However, the next year we

[8] *Regulatory* Issues *for* Medicare Providers (GAO-01-802R, June 11, 2001).

[9] To identify improper billing by a provider, CMS requires contractors to conduct a "probe" review of roughly 20 to 40 claims. If the probe sample indicates improper billing, the contractors determine the provider's overpayment amount by either selecting a statistically valid random sample of claims or basing the amount on a small sample that is not statistically representative.

[10] Medicare *Fraud and* Abuse: *DOJ's Implementation* of False Claims Act Guidance in National *Initiatives Varies* (GAO/HEHS-99-170, August 6, 1999).

reported that DOJ had made progress in incorporating the guidance into its ongoing investigations and had also developed a meaningful assessment of compliance in its periodic evaluations of U.S. Attorneys' Offices." Regarding corporate integrity agreements, we noted in our March 2001 report that these agreements were not always a standard feature of DOJ settlements." For example, 4 of 11 recent settlements that we reviewed were resolved without the imposition of such agreements.

Finally, some providers' concerns about the timeliness of the appeals process could be addressed by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which imposes deadlines at each step of the appeals process. For example, *initial* determination of a claim must be concluded within 45 days from the date of the claim, and redetermination must be completed within 30 days of receipt of the request. These revisions are scheduled to take effect on October 1, 2002.

CMS' Oversight of Contractors Is Key to Balancing Program Safeguards and Provider Concerns

CMS' oversight of its contractors is essential to ensuring that the Medicare program is administered efficiently and effectively. CMS is faced with the challenge of protecting program dollars and treating providers fairly. However, to accomplish these goals, contractors must implement CMS' policies fully and consistently. Historically, the agency's oversight of contractors has been weak, although it has made substantial improvements in the past 2 years. Continued vigilance in this area is critical as CMS tries to cope with known weaknesses and begins to rely on new specialty contractors for some of its payment safeguard activities.

Various Factors Have Contributed to *Weak* Contractor Oversight

Medicare's claims administration contractors are responsible for all aspects of claims administration, conduct particular safeguard activities, and are the primary source of Medicare communications to providers. However, oversight of Medicare contractors has historically been weak, leaving the agency without assurance that contractors are implementing program safeguards or paying providers appropriately. For years, HCFA's contractor performance and evaluation program (CPE)—its principal tool

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"*Medicare Fraud and Abuse: DOJ Has Made Progress in Implementing False Claims Act Guidance* (GAO/HEHS-00-73, March 31, 2000).

[12]*Medicare Fraud and Abuse: DOJ Has Improved Oversight of False Claims Act Guidance* (GAO-01-506, March 30, 2001).

used to evaluate contractor performance — lacked the consistency that agency reviewers need to make comparable assessments of contractor performance. HCFA reviewers had few measurable performance standards and little direction on monitoring contractors' payment safeguard activities. The reviewers in HCFAs 10 regional offices, who were responsible for conducting these evaluations, had broad discretion to decide what and how much to review as well as what disciplinary actions to take against contractors with performance problems.

This highly discretionary evaluation process allowed key program safeguards to go unchecked and led to the inconsistent treatment of contractors with similar performance problems. Dispersed responsibility for contractor activities across many central office components, limited information about how many resources are used or needed for contractor oversight, and late and outdated guidance provided to regional offices have also weakened contractor oversight.[13]

Over the years, we have made several recommendations to improve HCFAs oversight of its claims administration contractors. For example, we recommended that the agency strengthen accountability for evaluating contractor performanee. In response to our recommendations, HCFA has established an executive-level position at its central office with ultimate responsibility for contractor oversight, instituted national review teams to conduct contractor evaluations, and provided more direction to its regional offices through standardized review protocols and detailed instructions for CPE reviews.

Although the agency has taken a number of steps to improve its oversight efforts, our ongoing work suggests that opportunities for additional improvement exist. Last month, we joined CMS representatives as they conducted a CPE review at a contractor's telephone center. Although providers' ability to appropriately bill Medicare is dependent on their obtaining accurate and complete answers to their questions, the review focused primarily on adherence to call center procedures and the timeliness of responses to provider questions. Moreover, the CMS

[13]The weak oversight of contractors helped create an environment in which a number of HCFA contractors committed fraud. The fraud was not detected through the agency's oversight efforts but instead was reported by whistleblowers and resulted in settlements for millions of dollars. HCFA failed to uncover the contractors' fraudulent practices, in part, because it relied on contractor self-reporting of management controls and seldom independently validated contractor-provided information.

reviewer selected a small number of cases to evaluate—only 4 of the roughly 140,000 provider calls this center receives each year.

While CMS' management of claims administration contractors suffers from weak oversight, its contracting practices for selecting fiscal intermediaries and carriers may contribute to these difficulties. Unlike most of the federal government, the agency was exempted from conducting full and open competitions by the Social Security Act. Thus, for decades, HCFA has relied on many of the same contractors to perform program management activities, and has been at a considerable disadvantage in attracting new entities to perform these functions.

New Contracting Authority Provides Opportunity for Improving Safeguard Performance

Congress included provisions in HIPAA that provided HCFA with more flexibility in contracting for program safeguard activities. It allowed the agency to contract with any entity that was capable of performing certain antifraud activities. In May 1999, HCFA implemented its new contracting authority by selecting 12 program safeguard contractors—PSCs—using a competitive bidding process.[14] These entities represent a *mix* of health insurance companies, information technology businesses, and several other types of *firms.*

In May of this year, we reported on the opportunities and challenges that the agency faces as it integrates its PSCs into its overall program safeguard strategy.[15] The PSCs represent a new means of promoting program integrity and enable CMS to test a multitude of options. CMS is currently experimenting with these options to identify how PSCs can be most effectively utilized. For example, some PSCs are performing narrowly focused tasks that are related to a specific service considered to be particularly vulnerable to fraud and abuse. Others are conducting more broadly based work that may have national implications for the way program safeguard activities are conducted in the future or which may result in the identification of best practices.

[14]Almost all of the PSCs have had experience as Medicare contractors: as of May 2001, six were Medicare claims administration contractors and an additional five had other types of contracts with CMS. Two of the six PSCs *with* claims administration contracts have established new entities to perform PSC work.

[15]*Medicare: Opportunities and Challenges in Contracting for Program Safeguards* (GAO-01-616, May 18, 2001).

In our report, we recommended that the agency define the strategic directions for future use of the PSCs, including the establishment of long-term goals and objectives. We also recommended that clear, quantifiable performance measures and standards be established and related to well defined outcomes in order to lay the groundwork for meaningful future performance evaluations. We recognize that it will take some time for the agency to develop appropriate performance criteria, but believe it is important to start experimenting with different approaches, such as using performance-based contracts, and refine them as time goes on. This need for better performance measures, standards, and outcomes will become especially critical if CMS awards contracts that are performance-based and contain financial incentives and penalties.

Concluding Observations

Medicare is a popular program that millions of Americans depend on for covering their essential health needs. However, the management of the program has fallen short of expectations because it has not always appropriately balanced or satisfied beneficiaries', providers', and taxpayers' needs. Although the agency has taken some positive steps, weaknesses in its communications with providers and its oversight of contractors still exist. CMS' ability to successfully address these and other shortcomings will ultimately enhance its program safeguard activities and improve Medicare program operations.

This concludes my statement. I would be happy to answer any questions that you may have.

GAO Contact And Staff Acknowledgments

For further information regarding this testimony, please contact me at (312) 220-7767. Susan Anthony and Geraldine Redican-Bigott also made key contributions to this statement.

(290103)

Related GAO Products

Medicare Contracting Reform: Opportunities and Challenges in Contracting for Claims Administration Services (GAO-01-918T, June 28, 2001).

Medicare Management: Current and Future Challenges (GAO-01-878T, June 19, 2001).

Medicare: Opportunities and Challenges in Contracting for Program Safeguards (GAO-01-616, May 18, 2001).

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Balanced Budget Act: Any Proposed Fee-for-Service Payment Modifications Need Thorough Evaluation (GAO/T-HEHS-99-139, June 10, 1999).

Medicare+Choice: New Standards Could Improve Accuracy and Usefulness of Plan Literature (GAO/HEHS-99-92, Apr. 12, 1999).

Medicare Managed Care: Greater Oversight Needed to *Protect Beneficiary Rights* (GAO/HEHS-99-68, **Apr.** 12, 1999).

Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

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Regulating agency: HHS Office of Civil Rights (OCR)

Citation: Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164)

Authority: Health Insurance Portability and Accountability Act of 1996

Description of Problem: Protecting a patient's privacy already is part of a physician's daily practice. Adding substantial paperwork requirements, personnel and systems changes required by the regulation will take vital time and resources away from patient care and may not result in any significant improvement in patient confidentiality.

Recently proposed modifications will help alleviate some of the unintended consequences created by the final rule. No regulation should obstruct a patient's ability to get the proper care and medication he/she requires. However, we believe more can be done to streamline the final rule and reduce the rule's administrative burden while still protecting a patient's privacy.

Many small practices have a less formal office setup in comparison to large group practices. Adding more bureaucracy and paperwork such as appointing a privacy compliance officer, documenting privacy policies and procedures, will not ensure privacy protection. Since protecting a patient's privacy is already part of a physician's code of ethics and practice, we urge as much flexibility and discretion as possible when implementing this rule.

One of AOA's major concerns with the privacy rule relates to the Business Associate provision. The rule should be amended to provide that an entity is either a covered entity or a business associate, but not both, effectively eliminating the requirement for a business associate agreement between covered entities.

In addition, OCR must modify certain definitions as they pertain to private sector accrediting organizations. The American Osteopathic Association is an accrediting organization, approved by the Centers for Medicare and Medicaid Services (CMS). AOA's Healthcare Facilities Accreditation Program (HFAP) accredits: Hospitals, Clinical Laboratories, Ambulatory Care/Surgery Centers, Physical Rehabilitation Facilities, Behavioral Health Facilities and Critical Access Hospitals. HFAP already has privacy standards in place and has developed a surveyors' agreement to comply with privacy requirements.

The purpose of AOA's HFAP is to inspect facilities for compliance with requirements designed to assist the facilities in monitoring and improving the quality of care provided to their patients. Within the grant of authority from the federal government i.e., CMS, AOA's HFAP also provides a health care system oversight function on behalf of the federal government.

Under the privacy rule, private accrediting organizations are considered business associates, which require contracts with covered entities. The Business Associate provision creates added burdens and costs without improving privacy protection.

The AOA believes that a private sector accrediting group should be considered a health oversight agency when performing its accreditation activities recognized by the federal government, and it need not obtain business associate agreements from the facilities it accredits.

The definition of a "health oversight agency" does not include private organizations such as private sector accrediting groups, but we believe OCR should allow an exception when the accrediting organization is performing its accreditation activities as a federally recognized national accreditation organization. The same exception should be allowed in the definition of "business associate" when referring to accreditation.

We recognize that OCR took measures to alleviate the burdens caused by the Business Associate provision such as proposing a transition period as well as model contract language, however none of the measures alleviates physicians of the unreasonable responsibility and liability for unauthorized uses or disclosures of patient information by business associates.

Physicians should not be the enforcers of this rule. Any extension of privacy rules to entities not covered by HIPAA must be achieved through new legislation. Congress needs to enact comprehensive privacy legislation, which places responsibility on all users to fully protect health information.

Proposed Solution : *OCR needs to reduce the administrative costs as much as possible; include private sector accrediting groups in the definition of a health oversight agency; and eliminate the requirement that physicians be the enforcer of the regulations.*

December 28, 2000 (65 FR 82462, 82797). The proposed change with the most direct effect on federalism principles concerns the clarifications regarding the rights of parents and minors under State law. The modifications would make clear the intent of the Department to defer to State law with respect to such rights. Therefore, the Department believes that the modifications in this proposed Rule would not significantly affect the rights, roles and responsibilities of States.

Appendix to the Preamble — Model Business Associate Contract Provisions

Introduction

The Department of Health and Human Services provides these model business associate contract provisions in response to numerous requests for guidance. This is only model language. These provisions are designed to help covered entities more easily comply with the business associate contract requirements of the Privacy Rule. However, use of these model provisions is not required for compliance with the Privacy Rule. The language may be amended to more accurately reflect business arrangements between the covered entity and the business associate.

These or similar provisions may be incorporated into an agreement for the provision of services between the entities or they may be incorporated into a separate business associate agreement. These provisions only address concepts and requirements set forth in the Privacy Rule and alone are not sufficient to result in a binding contract under State law and do not include many formalities and substantive provisions that are required or typically included in a valid contract. Reliance on this model is not sufficient for compliance with state law and does not replace consultation with a lawyer or negotiations between the parties to the contract.

Furthermore, a covered entity may want to include other provisions that are related to the Privacy Rule but that are not required by the Privacy Rule. For example, a covered entity may want to add provisions in a business associate contract in order for the covered entity to be able to rely on the business associate to help the covered entity meet its obligations under the Privacy Rule. In addition, there may be permissible uses or disclosures by a business associate that are not specifically addressed in these model provisions. For example, the Privacy Rule does not preclude a business associate from disclosing protected health information to report unlawful conduct in accordance with § 164.502(j). However, there is not a specific model provision related to this permissive disclosure. These and other types of issues will need to be worked out between the parties.

Model Business *Associate* Contract Provisions[1]

Definitions (alternative approaches)

Catch-all definition:

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR 160.103 and 164.501.

Examples of specific definitions:

(a) Business Associate. "Business Associate" shall mean [Insert Name of Business Associate].

(b) Covered *Entity.* "Covered Entity" shall mean [Insert Name of Covered Entity].

(c) *Individual.* "Individual" shall have the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

(d) Privacy *Rule.* "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

(e) Protected Health Information, "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR 164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(f) Required *By Law.* "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR 164.501.

(g) *Secretary.* "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.

Obligations and Activities of Business Associate

(a) Business Associate agrees to not use or further disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law.

(b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

(c) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of *this* Agreement. **[This** provision may be included if it is appropriate for the Covered Entity to pass on its duty to mitigate damages by a Business Associate.]

(d) Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement.

(e) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.

(f) Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner designated by Covered Entity, to Protected Health Information in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR **164.524.** [Not necessary if business associate does not have protected health information in a designated record set.]

(g) Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of Covered Entity or ***an*** Individual, and in the time and manner designated by Covered Entity. [Not necessary if business associate does not have protected health information in a designate2 record set.]

(h) Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or . received by Business Associate on behalf of, Covered Entity available to the Covered Entity, **or** at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

(i) Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR **164.528.**

(j) Business Associate agrees to provide to Covered Entity or an Individual, in time and manner designated by Covered Entity, information collected in accordance with Section [Insert Section Number in Contract Where Provision (i) Appears] of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with **45** CFR **164.528.**

Permitted Uses and Disclosures *by* Business *Associate*

General Use and Disclosure Provisions (alternative approaches)

Specify purposes:

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for **the** following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity: [List Purposes].

Refer *to* underlying *services agreement:*

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform *functions,* activities, or services for, or on behalf of, Covered Entity as specified in [Insert Name of Services Agreement], provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity.

[1] Words or phrases contained in brackets are intended as either optional language or as instructions to the users of these model provisions and are not intended to be included in the contractual provisions.

Specific Use and Disclosure Provisions [only necessary if parties wish to allow Business Associate to engage in such activities]

(a) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

(b) Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(c) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 CFR 164.504(e)(2)(i)(B).

Obligations of Covered Entity

Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions [provisions dependent on business arrangement]

(a) Covered Entity shall provide Business Associate with the notice of privacy practices that Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

(b) Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect Business Associate's permitted or required uses and disclosures.

(c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR 164.522.

Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. [Include an exception if the Business Associate will use or disclose protected health information for, and the contract includes provisions for, data aggregation or management and administrative activities of Business Associate].

Term and Termination

[a) *Term.* The Term of this Agreement shall be effective as of [Insert Effective Date], and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.

(b) *Termination for Cause.* Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement [and the ___ Agreement/sections ___ of the ___ Agreement] if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, or immediately terminate this Agreement [and the ___ Agreement/sections ___ of the ___ Agreement] if Business Associate has breached a material term of this Agreement and cure is not possible. [Bracketed language in this provision may be necessary if there is an underlying services agreement. Also, opportunity to cure is permitted, but not required by the Privacy Rule.]

(c) *Effect of Termination.*

(1) Except as provided in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

(2) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

Miscellaneous

(a) *Regulatory References.* A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.

(b) *Amendment.* The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104–191.

(c) *Survival.* The respective rights and obligations of Business Associate under Section [Insert Section Number Related to "Effect of Termination"] of this Agreement shall survive the termination of this Agreement.

(d) *Interpretation.* Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule.

List of Subjects

45 CFR *Part 160*

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

45 CFR Part 164

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

Dated: March 12, 2002.

Tommy G. Thompson,

Secretary.

For the reasons set forth in the preamble, the Department proposes to amend 45 CFR Subtitle A, Subchapter C, as follows:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 continues to read as follows:

Authority: Sec. 1171 through 1179 of the Social Security Act, (42 U.S.C. 1320d–1329d–8) as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031 and sec. 264 of Pub. L. 104–191 (42 U.S.C. 1320d–2(note)).

§ 160.102 [Amended]

2. Amend § 160.102(b), by removing the phrase "section 201(a)(5) of the Health Insurance Portability Act of 1996, (Pub. L. 104–191)" and adding in its place the phrase "the Social Security Act, 42 U.S.C. 1320a–7c(a)(5)".

3. In § 160.103 add the definition of "individually identifiable health information" in alphabetical order to read as follows:

§ 160.103 Definitions.

* * * * *

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the

information can be used to identify the individual.

* * * * *

4. In § 160.202 revise paragraphs (2) and (4) of the definition of "more stringent" to read as follows:

§ 160.202 Definitions.

* * * * *

More stringent means * * *

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

* * * * *

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

* * * * *

§ 160.203 [Amended]

5. Amend § 160.203(b) by adding the words "individually identifiable" before the word "health".

PART 164—SECURITY AND PRIVACY

Subpart E—Privacy of Individually Identifiable Health Information

1. The authority citation for part 164 continues to read as follows:

Authority: 42 U.S.C. 1320d–2 and 1320d–4, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)).

§ 164.102 [Amended]

2. Amend § 164.102 by removing the words "implementation standards" and adding in its place the words "implementation specifications."

§ 164.500 [Amended]

3. In § 164.500, remove "consent," from paragraph (b)(1)(v).

§ 164.501 [Amended]

4. Amend § 164.501 as follows:

a. In the definition of "health care operations" remove from the introductory text of the definition ", and any of the following activities of an organized health care arrangement in which the covered entity participates" and revise paragraphs (6)(iv) and (v).

b. Remove the definition of "individually identifiable health information".

c. Revise the definition of "marketing".

d. In paragraph (1)(ii) of the definition of "payment," remove the word "covered".

e. Revise paragraph (2) of the definition of "protected health information".

The revisions read as follows:

§ 164.501 Definitions.

* * * * *

Health care operations means * * *

(6) * * *

(iv) The sale, transfer, merger, or consolidation of all or part of a covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information and fundraising for the benefit of the covered entity.

* * * * *

Marketing means to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service. *Marketing* excludes a communication made to an individual:

(1) To describe the entities participating in a health care provider network or health plan network, or to describe if, and the extent to which, a product or services (or payment for such product or service) is provided by a covered entity or included in a plan of benefits;

(2) For treatment of that individual; or

(3) For case management or care coordination for that individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to that individual.

* * * * *

Protected health information means * * *

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

* * * * *

5. Amend § 164.502 as follows:

a. Revise paragraphs (a)(1)(ii), (iii), and (vi).

b. Revise paragraph (b)(2)(ii).

c. Redesignate paragraphs (b)(2)(iii) through (v) as paragraphs (b)(2)(iv) through (vi).

d. Add a new paragraph (b)(2)(iii).

e. Redesignate paragraphs (g)(3)(i) through (iii) as (g)(3)(i)(A) through (C) and redesignate paragraph (g)(3) as (g)(3)(i).

f. Add new paragraphs (g)(3)(ii) and (iii).

The revisions and additions read as follows:

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) *Standard.* * * *

(1) *Permitted uses and disclosures.* * * *

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) As incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of § 164.502(b), § 164.514(d), and § 164.530(c) with respect to such otherwise permitted or required uses or disclosures;

* * * * *

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(f) and (g).

* * * * *

(b) *Standard: Minimum necessary.* * * *

(2) *Minimum necessary does not apply.* * * *

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under § 164.508;

* * * * *

(g)(1) *Standard: Personal representatives.* * * *

(3) *Implementation specification: unemancipated minors.*

(i) * * *

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) A covered entity may disclose protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis* if an applicable provision of State or other law, including applicable case law, permits or requires such disclosure; and

(B) A covered entity may not disclose protected health information about an unemancipated minor to a parent, guardian, or other person acting in *loco parentis* if an applicable provision of State or other law, including applicable case law, prohibits such disclosure.

(iii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section, a covered entity must, consistent with State or other applicable law, provide a right of access, as set forth in § 164.524 to either:

(A) A parent, guardian, or other person acting in loco parentis, as the personal representative of the unemancipated minor;

(B) The unemancipated minor; or

(C) Both.

* * * * *

6. Amend § 164.504 as follows:

a. In paragraph (a), revise the definitions of "health care component" and "hybrid entity".

b. Revise paragraph (c)(1)(ii).

c. Revise paragraph (c)(3)(iii).

d. Revise paragraph (f)(1)(i).

e. Add paragraph (f)(1)(iii).

The revisions and addition read as follows:

§ 164.504 Uses and disclosures: Organizational requirements.

(a) Definitions. * * *

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with paragraph (c)(3)(iii) of this section.

Hybrid entity means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph (c)(3)(iii) of this section.

* * * * *

(c)(1) Implementation specification: Application of other provisions. * * *

(ii) A reference in such provision to a "health plan," "covered health care provider," or "health care clearinghouse" refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable; and

* * * * *

(3) Implementation specifications: Responsibilities of the covered entity.

* * *

(iii) The covered entity is responsible for designating the components that are part of one *or* more health care components of the covered entity and documenting the designation as required by § 164.530(j), provided that if the covered entity designates a health care component or components, it must include any component that would meet the definition of covered entity if it were a separate legal entity. Health care component(s) may include a component that performs:

(A) covered functions; and

(B) activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities.

* * * * *

(f)(1) Standard: Requirements for group health plans. (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

* * * * *

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan to the plan sponsor.

* * * * *

7. Revise § 164.506 to read as follows:

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) Standard: Permitted *uses* and disclosures. Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) Standard: Consent permitted. (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent of an individual under this paragraph shall not be effective to permit a use or disclosure of protected health information that is not otherwise permitted or required by this subpart.

(c) Implementation specifications: Treatment, payment, *or* health care operations.

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of another health care provider.

(3) A covered entity may disclose protected health information to another covered entity or health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if both entities have a relationship with the individual who is the subject of the protected health information being requested, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

8. Amend § 164.508 as follows:

a. Remove "consistent with consent requirements in § 164.506" in paragraph (a)(2)(i).

b. Add "the" before "originator" in paragraph (a)(2)(i)(A).

c. Remove the word "in" after the term "covered entity" and add in its place the words "for its own" in paragraph (a)(2)(i)(B).

d. Add the words "itself in" after the word "defend" in paragraph (a)(2)(i)(C).

e. Add paragraph (a)(3).

f. Revise paragraphs (b)(1)(i).

g. Remove the word "be" in paragraph (b)(1)(ii).

h. Remove ", (d), (e), or (f)" from paragraph (b)(2)(ii).

i. Remove paragraph (b)(2)(iv).

j. Redesignate paragraphs (b)(2)(v) and (vi) as paragraphs (b)(2)(iv) and (v).

k. Add "or (4)" after "(b)(3)" in redesignated paragraph (b)(2)(iv).

l. Revise paragraphs (b)(3)(i).

m. Add a comma after the term "psychotherapy notes" in paragraph (b)(3)(iii).

n. Remove "under paragraph (f) of" and add in its place "for the use or disclosure of protected health information for such research under" in paragraph (b)(4)(i).

o. Add the word "and" at the end of paragraph (b)(4)(ii)(B).

p. Remove paragraph (b)(4)(iii).

q. Redesignate paragraph (b)(4)(iv) as paragraph (b)(4)(iii).

r. Add "or the policy itself' after the word "policy" in paragraph (b)(5)(ii).

s. Remove paragraphs (d),(e), and (f).

t. Revise paragraph (c).

The revisions and addition read as follows:

§ 164.508 Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures.* * * *

(3) *Authorization required: Marketing.*

(i) Notwithstanding any other provision of this subpart other than § 164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing is expected to result in direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is expected.

* * * * *

(b) *Implementation specifications:* General requirements. * * *

(1) *Valid authorizations.*

(i) A valid authorization is a document that meets the requirements in paragraphs (c)(1) and (2) of this section.

* * * * *

(3) *Compound authorizations.* * * *

(i) An authorization for the use or disclosure of protected health information for a specific research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

* * * * *

(c) *Implementation specifications: Core elements and requirements.* (1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The following statements meet the requirements for an expiration date or an expiration event if the appropriate conditions apply:

(A) The statement "end of the research study" or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research.

(B) The statement "none" or similar language is sufficient if the authorization is for the covered entity to use or disclose protected health information for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization: or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this rule.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

9. Amend § 164.510 as follows:

a. Revise the first sentence of the introductory text.

b. Remove the word "for" from paragraph (b)(3).

The revision reads as follows:

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. * * *

* * * * *

10. Amend § 164.512 as follows:

a. Revise the section heading and the first sentence of the introductory text.

b. Revise paragraph (b)(1)(iii).

c. In paragraph (b)(1)(v)(A) remove the word "a" before the word "health."

d. Add the word "and" after the semicolon at the end of paragraph (b)(1)(v)(C).

e. Redesignate paragraphs (f)(3)(ii) and (iii) as (f)(3)(i) and (ii).

f. In the second sentence of paragraph (g)(2) add the word "to" after the word "directors."

g. In paragraph (i)(1)(iii)(A) remove the word "is" after the word "disclosure."

h. Revise paragraph (i)(2)(ii).

The revisions read as follows:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section,

subject to the applicable requirements of this section. * * *

* * * * *

(b) *Standard: uses and disclosures for public health activities.*

(1) *Permitted disclosures.* * * *

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products:

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance:

* * * * *

(i) *Standard: Uses and disclosures for research purposes.* * * •

(2) *Documentation of waiver approval.* * * *

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

* * * * *

11. Amend § 164.514 as follows:

a. Revise paragraph (b)(2)(i)(R).

b. Revise paragraph (d)(1).

c. Revise paragraph (d)(4)(iii).

d. Remove and reserve paragraph (e).

The revisions read as follows:

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

* * * * *

(b) *Implementation specifications: Requirements for de-identification of protected health information.* * * *

(2)(i) * * *

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

* * * * *

(d)(1) *Standard: minimum necessary requirements.* In order to comply with § 164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for or the use and disclosure of protected health information.

* * * * *

(4) *Implementation specifications: Minimum necessary requests for protected health information.* * * *

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

* * * * *

(e) [Removed and Reserved]

* * * * *

12. Amend § 164.520 as follows:

a. Remove the word "consent or" from paragraph (b)(1)(ii)(B).

b. Revise paragraph (c)(2)(i).

c. Redesignate paragraphs (c)(2)(ii) and (iii) as (c)(2)(iii) and (iv).

d. Add new paragraph (c)(2)(ii).

e. Amend redesignated paragraph (c)(2)(iv) by removing "(c)(2)(ii)" and adding in its place "(c)(2)(iii)".

f. Revise paragraph (c)(3)(iii) by adding a sentence at the end.

g. Revise paragraph (e).

The revisions and addition read as follows:

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(c) *Implementation specifications: provision of notice.* * * •

(2) *Specific requirements for certain covered health care providers.* * * *

(i) Provide the notice:

(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

* * * * *

(3) *Specific requirements for electronic notice.* • * *

(iii) * * * The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

* * * * *

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

§ 164.522 [Amended]

13. Amend § 164.522 by removing the reference to "164.502(a)(2)(i)" in paragraph (a)(1)(v), and adding in its place "164.502(a)(2)(ii)".

14. Amend § 164.528 as follows:

a. In paragraph (a)(1)(i), remove "§ 164.502" and add in its place "§ 164.506".

b. Redesignate paragraphs (a)(1)(iii) through (vi) as (a)(1)(iv) through (vii).

c. Add paragraph (a)(1)(iii).

d. Revise paragraph (b)(2)(iv) in its entirety.

e. Remove "or pursuant to a single authorization under § 164.508," from paragraph (b)(3).

The addition and revision read as follows:

§ 164.528 Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.*

(1) * * *

(iii) Pursuant to an authorization as provided in § 164.508.

* * * * *

(b) Implementation specifications: Content of the accounting. * * *

(2) * * *

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.

* * * * *

15. Amend § 164.530 as follows:

a. Redesignate paragraph (c)(2) as (c)(2)(i).

b. Add paragraph (c)(2)(ii).

c. Remove the words "the requirements" from paragraph (i)(4)(ii)(A) and add in their place the word "specifications."

The addition reads as follows:

§ 164.530 Administrative requirements.

* * * * *

(c) *Standard: Safeguards.* * * *

(2) *Implementation specifications: Safeguards.* (i) * * *

(ii) A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

* * * * *

16. Revise § 164.532 to read as follows:

§ 164.532 Transition Provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting **the use** or disclosure of protected health information, informed consent of the individual to participate in research, or a waiver of informed consent by an IRB.

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in § 164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a).

(c) *Implementation Specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may use or disclose, for a specific research study, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a) and that the covered entity has obtained, prior to the applicable compliance date, either:

(1) The authorization or other express legal permission from an individual to use or disclose protected health information for the research study:

(2) The informed consent of the individual to participate in the research study; or

(3) A waiver, by an IRB, of informed consent for the research study, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research study.

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this subpart, a covered entity, other than a small health plan, may disclose protected health information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.502(e) and 164.504(e) consistent with the requirements, and only for such time, set forth in paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance.* — *(1) Qualification.* Notwithstanding other sections of this subpart, a covered entity, other than a small health plan, is deemed to be in compliance with the documentation and contract requirements of §§ 164.502(e) and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to the effective date of this provision, such covered entity has entered into and is operating pursuant to a written contract or other written arrangement with a business associate for such business associate to perform functions or activities or provide services that make the entity a business associate; and

(ii) The contract or other arrangement is not renewed or modified from the effective date of this provision and until the compliance date set forth in § 164.534.

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section, shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after the compliance date set forth in § 164.534; or

(ii) April 14, 2004.

(3) *Covered entity responsibilities.* Nothing in this section shall alter the requirements of a covered entity to comply with part 160, subpart C of this subchapter and §§ 164.524, 164.526, and 164.528 with respect to protected health information held by a business associate.

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