VEDDER PRICE

Health Care Bulletin

If you have any questions regarding material in this issue of the *Health Care Bulletin* please contact the contributing author: Kathryn L. Stevens (312/609 -7803) or kstevens@vedderprice.com.

If you have suggestions for a specific topic you would like addressed in a future issue, please contact Richard H. Sanders *(practice leader)* at 312/609 -7644.

May, 2001

In This Issue:

HIPAA PRIVACY RULE TAKES EFFECT AS SCHEDULED

On Thursday, April 12, 2001, Department of Health and Human Services ("HHS") Secretary Tommy Thompson issued a press release announcing that HHS would take steps immediately to implement the patient privacy protections contained within the Health Insurance Portability and Accountability Act ("HIPAA"). This Vedder Price Bulletin is intended to alert you to the potential reach of new regulations that have been promulgated under HIPAA and their impact on individuals and entities within the health care industry, as well as on individuals and organi-zations that provide services to the health care industry.

Background History of HIPAA and the Privacy Rule

HIPAA, enacted in 1996, provides for new and complex standards governing health information security, the codification of standard health transactions, and the maintenance of privacy and confidentiality of individually identifiable health information. Providers and health plans (including self-insured employer plans covering 50 employees or more), as well as individuals or organizations that receive such information from providers or health plans, are subject to the broad reach of this new regulatory scheme.

Last December, the Clinton administration released regulations governing the privacy of individually identifiable

health information transmitted or maintained in any form ("protected health information"). The regulations, referred to in this Bulletin as the Privacy Rule, impact every interaction and transaction involving protected health infor-mation, whether electronic, written, or oral. The Privacy Rule originally was scheduled to take effect in February 2001, but the Bush administration postponed that date and opened a public comment period, which expired on March 30, 2001. During that time, HHS received and reviewed more than 24,000 written comments. Although Secretary Thompson did not modify the Privacy Rule at the close of the comment period, he indicated that his office staff would keep in mind the comments received as they begin the process of issuing guidelines on how the rule should be implemented.

The Privacy Rule took effect on April 14, 2001. Health plans, health providers and individuals or organizations with whom they deal or from whom they receive services (their "business associates"), however, have until April 14, 2003 to comply. Small health plans have until April 14, 2004 to comply. Although the lead time seems long, the complexity of the Privacy Rule and the number of interpretive issues that will have to be resolved may make this lead time period barely long enough.

The Privacy Rule in Detail

The Privacy Rule affects most medical records and nearly every health care provider, health care billing entity, and health plan, as well as any of their business associates who have access to protected health information. The Privacy Rule requires several significant changes in the business activities of these organizations, including the imposition of additional requirements that must be met before providers and health plans may disclose protected health information. Thus, many of us (both within and outside of the health care industry) will be impacted by the Privacy Rule in the ordinary course of business.

Uses and Disclosures of Protected Health Information. The general rule is that a health plan or health care provider may use or disclose protected health information pertaining to an individual only: (i) to that individual; (ii) pursuant to a valid consent to carry out treatment, payment, or health care opera-tions; or (iii) in certain limited situations, such as emergencies, without consent of the individual.

Except where the Privacy Rule requires or permits release of

protected health information, health plans or providers must obtain written permission from patients for use or disclosure of their protected health information. The Privacy Rule delineates between the proper form that the written permission must take; certain situations mandate a "consent" and other situations require an "authorization."

A general consent is necessary for the use or disclosure of protected health information for treatment, payment, or health care operations. This consent may be written in general terms and address the entity's own privacy practices. If a single document is used to obtain consent for the use or disclosure of protected health information and for other activities, such as obtaining treatment, the consent for the use or disclosure of protected health information must be visually and organizationally separate from other consents and must be separately signed and dated by the individual.

Using or disclosing protected health information for specific purposes other than those addressed in the general consent (e.g., in connection with a law-suit or for employment determinations), however, necessitates a more specific written "authorization" from the patient. A valid authorization must contain certain core elements, which identify the information that may be disclosed and the limited purpose for the disclosure. Specifically, an authorization must contain the following information: (i) a description of the information to be used or disclosed; (ii) the name of the person(s) authorized to make the requested use or disclosure; (iii) the name of the person(s) to whom the provider may make the use or disclosure; (iv) an expiration date or an expiration event; (v) a statement of the individual's right to revoke his or her authorization; (vi) a statement that information used or disclosed pursuant to the authorization may be subject to redisclosure by the recipient and no longer be protected by the Privacy Rule; (vii) signature of the individual and date; and (viii) if the authorization is signed by a personal representative of the individual, a description of such individual's authority.

Generally, an authorization may not be combined with any other document. For example, if the organization's relationship with a patient is primarily for treatment purposes, but it often discloses health information to a central database for research purposes, the patient must sign both a consent form for use or disclosure of protected health information in connection with treatment, payment, and health care operations and a separate authorization to

disclose such information for research. There are three exceptions to this prohibition. First, an authorization for the use or disclosure of protected health information created for research that includes treatment of the individual (e.g., clinical trials) may be combined with a general consent for the use or disclosure of that information for treatment, payment, or health care operations and certain other documents. Second, authorizations for the use or disclosure of psychotherapy notes for multiple purposes may be combined in a single document, but may not be combined with authorizations for the use or disclosure of other protected health information. Finally, authorizations for the use or disclosure of protected health information (other than psycho-therapy notes) may be combined, provided the organization does not condition the provision of treatment, payment, enrollment, or eligibility on obtaining the authorization.

In light of the detailed nature of the specific use and disclosure requirements, every consent form in current use will have to be reviewed to ensure compliance with the specific use and disclosure requirements.

Limitations on Use or Disclosure of Protected Health Information. When using or disclosing protected health information, a health care provider or health plan must make reasonable efforts to limit the use or disclosure to only the minimum necessary to accomplish the intended use or disclosure. The determination of how much information is minimally necessary should be based upon policies that are in place to assess the extent of the information that will be disclosed and the reasonableness of taking steps to de-identify the information before disclosure. Information that has been de-identified, or removed of any data that can be used to identify the individual, is not considered protected health infor-mation and may be freely disclosed. The use and disclosure policies of every health plan and provider will need to be reviewed to make sure they encompass these additional requirements.

Written Contracts with Business Associates. A "business associate" is a person who, or entity that, performs or assists the provider or health plan to perform a function on behalf of the provider or health plan, or provides a service to the provider or health plan. In some instances, this definition would include legal counsel. A health provider or health plan may share protected health information of an individual with its business associates without further authori-zation from

that individual if it enters into a written contract with the business associate. The business associate contract must contain specific provisions addressing the restrictions on the business associate's use and disclosure of the information provided to it. A provider or health plan does not need a business associate contract with members of its own workforce. Similarly, the Privacy Rule permits two or more legally distinct providers and/or plans that share common ownership or control to designate themselves together as a single entity, thereby eliminating the need for a business associate agreement.

A business associate may use protected health information for its own activities, provided its actions conform with the terms of the business associate contract. A business associate may be required to give assurances with respect to safeguards for maintaining confidentiality or compliance with use restrictions. The appropriate scope of such assurances and the need for verification will have to be considered by the parties and measured against evolving regulatory requirements. A business associate may disclose protected health information to others if it also obtains assurances that the information will be held in confidence and that the recipient will notify the business associate of breaches of confidentiality. If feasible, a business associate should destroy or return protected health information after a certain period of time. What constitutes destruction or return in the context of the digital/computer age also will have to be determined over time.

A health plan or provider that knows a business associate is engaging in activities that constitute a material breach of the contract must take reasonable steps to remedy or end the violation. If such steps are unsuccessful, the plan or provider must terminate the contract.

Certain Requirements for Group Health Plans. Many employers and other plan sponsors often perform functions that are integrally related to, or very similar to, the functions of a group health plan and, in carrying out such functions, may require access to protected health information maintained by the health plan. Accordingly, the Privacy Rule specifically addresses the circumstances under which a health plan may disclose an individual's protected health information to a plan sponsor without obtaining additional authorization from the individual. The Privacy Rule allows group health plans, and any HMO or other health insurance issuer with which it contracts, to disclose protected health

information to a plan sponsor if the plan sponsor agrees to use and disclose the information only as permitted or required by HIPAA. The health plan is not required to have a business associate agreement with the plan sponsor, provided certain conditions of the Privacy Rule are met. Generally, in order for a plan to disclose protected health information to a plan sponsor, the plan documents under which the plan was established must be amended to: (1) describe the permitted uses and disclosures of protected health information; (2) specify that disclosure is permitted only upon receipt of a certification from the plan sponsor that the plan documents have been amended, and the plan sponsor has agreed to certain conditions regarding the use and disclosure of protected health information; and (3) provide adequate firewalls to identify the classes of employees who may have access to protected health information, and restrict access to only those employees and only for the functions performed on behalf of the group health plan. The plan documents also must be amended to provide a mechanism for resolving issues of noncompliance. The Privacy Rule sets forth various assurances that must be included in the certification given by the plan sponsor to the group health plan.

Practical Application

Given the events of the past four months, there justifiably has been a considerable amount of confusion about the status of HIPAA and the Privacy Rule, as well as about what exactly individuals and organizations should be doing. Now that the Privacy Rule has taken effect, there is plenty to do in preparation for the implementation date, which is scheduled for April 14, 2003.

We have assembled a list of practical sugges-tions that should help health plans, providers, and other organizations achieve compliance over the next two years:

- Organizations should designate an individual within the organization to assume HIPAA-compliance responsibility, possibly creating a Privacy Official position

- Specific security and privacy policies and procedures should be developed to protect health information and individual rights and to govern the disclosure of such information

- Consent forms and medical records releases currently

in use should be reviewed to determine whether specific requirements as set forth in the Privacy Rule are met

- Employers, who are not otherwise covered under the Privacy Rule, should consider what impact the Privacy Rule will have on their ability to access employees' health information (including, where appropriate, developing and implementing protective measures to safeguard the confidentiality of employee medical records maintained on-site by the employer)
- Group health plan documents should be reviewed to determine whether they satisfy the Privacy Rule
- Employers who sponsor self-insured health plans should address potential conflicts that may arise when operating as both an employer and a health plan (e.g., determine which individuals in the organization must have access to employees' protected health information to fulfill their job responsibilities)
- Current contracts and agreements with outside vendors and service providers who have access to protected health information should be reviewed to determine whether they are "business associate agreements" and, if so, whether they meet the Privacy Rule requirements
- Negotiations with prospective vendors and service providers who will have access to protected health information should include appropriate HIPAA considerations, and any resulting contracts and agreements should satisfy the Privacy Rule requirements
- Organizations should begin educating staff members, directors, and officers about HIPAA, the Privacy Rule, and associated compliance issues
- Future training needs should be assessed and a tentative training schedule should be formulated

Implementing these tasks may entail a considerable amount of time and effort, particularly for larger organizations. For that reason, we believe that taking advantage of some, if not all, of these suggestions as early as possible will be advantageous, both practically and economically, to all individuals and organizations affected by HIPAA and the Privacy Rule.

Return to Top of Document

CONGRESSIONAL LEADERS PROPOSE BIPARTISAN PATIENT PROTECTION ACT OF 2001

Senators John McCain (R-AZ) and Edward Kennedy (D-MA), and Representatives John Dingell (D-MI) and Greg Ganske, MD (R-IA), proposed the Bipartisan Patient Protection Act of 2001 ("BPPA") earlier this year. The proposed legislation, which closely mirrors the Norwood-Dingell measure that passed the House during the last session of Congress, addresses patients' rights and provides incentives to expand health care coverage. BPPA would cover everyone insured by employer-based health plans, allow for choice of physician, ensure that external reviews of medical decisions are conducted by independent and qualified physicians, and hold health plans accountable when their decisions result in patient injury or death.

President Bush, who campaigned on a promise to enact patients' rights legislation, has indicated that he is committed to working with bipartisan Congressional leaders to enact such legislation in the near future. After reviewing BPPA, however, he has voiced concerns about certain aspects of it with which he disagrees.

The Proposed Legislation

BPPA is comprised of two bills, Senate Bill 283 ("S. 283"), and House Bill 526 ("H.R. 526"), which were introduced simultaneously in each house. BPPA is divided into several components that would amend the Public Health Service Act ("PHSA"), the Employee Retirement Income Security Act of 1974 ("ERISA"), and the Internal Revenue Code of 1986 (the "Code") to protect consumers in managed care plans and other forms of health coverage.

Summary of Major Provisions

Utilization Review; Right to Internal and External Appeals. Under the proposed legislation, group health plans would be required to conduct utilization review only in accordance with the provisions of benefits under such plan. BPPA would also require a periodic review of the 'clinical appropriateness'

national, full-service law firm with approximately 190 attorneys in Chicago, New York and New Jersey.

The Health Care Group

Vedder Price provides a broad range of services to its health care clients, including:

- Federal and state regulatory counseling to health care providers on tax exemption, Medicare/Medicaid, antitrust, fraud and abuse/Stark legislation, Certificate of Need, licensure, corporate practice of medicine and other issues;
- Regulatory compliance counseling for managed care organizations and other strategic health care financing or provider arrangements;
- Structuring of corporate networks, mergers, affiliations and acquisitions, including purchases and sales of practices and institutions;
- Comprehensive counseling to professional health care associations and medical specialty societies;
- Counseling regarding the corporate and regulatory impact of the implementation of strategic initiatives by health care entities, such as primary care satellite programs, physician recruitment and retention initiatives, and program development in ancillary areas such as home health and outpatient mental health;
- Tax-exempt and taxable financing (both as borrowers' and underwriters' counsel); and
- Development of innovative responses to Medicaid and other publicly funded managed care initiatives.

Principal Members of the Health Care Practice:

Richard H. Sanders
(312/609-7644)
Michael G. Beemer
(312/609-7630)
Michael E. Reed
(312/609-7640)
Robert J. Moran
(312/609-7517)
William F. Walsh
(312/609-7730)
Thomas G. Abram
(312/609-7760)
Douglas J. Polk
Gregory G. Wrobel
(312/609-7722)
Kathryn L. Stevens
(312/609-7803)

of a sample of denials of claims for benefits.

BPPA provisions would prohibit contingent compensation arrangements that encourage or reward the denial of benefits. Additionally, BPPA would foster accessibility by requiring that personnel performing utilization review are accessible by toll-free telephone numbers during regular business hours. BPPA would limit the frequency of utilization review with respect to services furnished to any particular individual, and allow review only where reasonably required to assess whether services under review are medically necessary and appropriate.

BPPA would mandate that health plans and programs afford participants at least 180 days to file an internal appeal relating to the denial of a claim. Participants also would be allowed to make oral requests for an appeal where the factors necessitate an expedited or concurrent determination. Any internal review based on the denial of a claim would need to be conducted by an individual with expertise in the appropriate area of medicine who was not involved in the initial adverse determination. Further, BPPA would impose a requirement on health plans to provide written notice of the internal review determination to both the participant and the treating health care professional within two days after completing the review, if not sooner. BPPA also would allow group health plans to waive the internal review process and allow participants the option of proceeding directly to external review.

According to provisions of the proposed bill, each plan would be required to afford participants access to independent, external review by a licensed physician or health care professional after receiving a denial of a claim for benefits, provided the participants file requests for such review no later than 180 days after the initial internal denial.

BPPA would require that, upon receiving a request for external review from a participant, the health plan immediately forward its initial internal decision to a designated external review entity, which must render a determination on the denial of a claim within 21 days after receiving the request for external review.

Access to Care. Under BPPA, a health plan that requires or provides for designation of a participating primary care provider ("PCP") would be required to allow the designation of any participating PCP who is available to accept the

participant. Additionally, health plans could not prohibit or limit access to qualified physicians in order to receive medically necessary and appropriate specialty care, unless the participant fails to follow appropriate referral procedures.

If a plan provides benefits for out-of-network emergency services without the need for prior authorization, BPPA would prohibit the plan from holding participants liable for amounts that exceed the amount that would be incurred if the participant had received the same services from a participating health care provider with prior authorization.

Access to Needed Prescription Drugs. To the extent that a plan provides coverage for prescription drugs and limits coverage to drugs in a specified formulary, BPPA would require that the plan or issuer: (a) ensure participation of physicians and pharmacists in the development and review of the formulary; (b) provide for disclosure of the formulary to providers; and (c) in accordance with quality assurance and utilization review standards of the plan, provide for exceptions where a non-formulary alternative is medically necessary and appropriate.

Provision of Information to Participants. To better facilitate patient access to information, BPPA would require that health plans provide for disclosure of certain information to participants on an annual basis. Information provided to participants shall include any specific exclusions or express limitations of benefits, and any definition of 'medical necessity' used in making coverage determinations by the plan. If a plan implements a reduction in benefits, it would be required to advise participants in writing of the reduction at least 30 days prior to the date on which the reduction takes effect.

Prohibition of Interference with Certain Medical Communications. BPPA would prohibit "gag clauses," which refers to language in contracts between plans and providers that prohibits or restricts providers from advising patients about their health status or possible treatment alternatives if benefits for such care are not provided under the plan.

President Bush's Standards

In a speech to the American College of Cardiology on March 21, 2001, President Bush stressed the need for managed care reform. In his remarks, President Bush stated that BPPA did not meet his standards for a Patients' Bill of

Vedder, Price, Kaufman & Kammholz
A Partnership including Vedder, Price, Kaufman & Kammholz, P.C.

Chicago
222 North LaSalle Street
Chicago, Illinois 60601
312/609-7500
Facsimile: 312/609-5005

New York
805 Third Avenue
New York, New York 10022
212/407-7700
Facsimile: 212/407-7799

New Jersey
354 Eisenhower Parkway
Plaza II
Livingston, New Jersey 07039
973/597-1100
Facsimile: 973/597-9607

Rights. In particular, he emphasized the need for comprehensive coverage for all Americans with private health insurance, which includes a rapid and binding independent medical review process for denials of care. President Bush also indicated that appropriate legislation should include a cap on damages to avoid driving up insurance premiums and adequate safeguards to ensure that employers are not subject to frivolous or multiple state lawsuits.

The appropriate scope of health plan liability undoubtedly will remain a key area of dispute. While BPPA allows plaintiffs to file lawsuits in state courts over medical decisions and in federal courts over administrative decisions, President Bush's principles state that health plans should be held liable only in federal court. Moreover, President Bush is opposed to employers being subjected to unlimited punitive damages under multiple state lawsuits. While BPPA subjects employers to liability only if they directly participate in a decision to deny a claim for benefits, President Bush has stated that this provision does not protect employers from unnecessary litigation, as it forces them to prove they were not involved in the decision to deny coverage. Further, President Bush has denounced the $5,000,000.00 cap on federal damages under BPPA as excessive and has insisted that any federal bill have "reasonable caps" on damages.

Despite the uncertainty pertaining to the liability provisions, BPPA appears to satisfy the President's standards relating to binding independent internal and external review. BPPA also provides for direct access to emergency care, specialty care, and obstetric and gynecological care, and requires health plans to afford individuals the opportunity to designate a pediatrician as a primary care provider for young participants, all of which President Bush has included in his standards for patients' rights.

Practical Impact

President Bush and bipartisan Congressional leaders are working to enact patients' rights legislation this term. The precise structure of the final piece of legislation, however, remains uncertain. President Bush has indicated his approval of several aspects of BPPA (such as those relating to quality patient care), but also has indicated his opposition to certain other provisions (such as the appropriate venue for resolving disputes). Thus it appears that it will be necessary for both sides to compromise in order to pass BPPA this year.

- Return to the Health Care index.
- Return to the Vedder Price Publications Page.
- Return to: Top of Page.

Home | Legal Services | Attorneys | **Publications** | Recruiting | Seminars | Speakers | Alumni
Contact Us | Search

Top of Page