August 1, 2011

Georgina Verdugo, JD, LLM, MPA
Director
HHS Office for Civil Rights
Attention: HIPAA Privacy Rule Accounting of Disclosures
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

RE: HIPAA Privacy Rule Accounting of Disclosures – 45CFR164; RIN0991-AB62

Dear Madam Director:

On behalf of the Healthcare Billing and Management Association's (HBMA) over 750 member companies, we are pleased to submit our comments on the Office of Civil Rights Notice of Proposed Rulemaking (NPRM) regarding the HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology Economic and Clinical Health Act (HITECH) as published in the May 31, 2011 *Federal Register*.

HBMA is a non-profit trade association of companies providing medical billing and related services to physicians, hospitals, non-physicians (ambulance, DME, ASC, IDTF, Rural Health Clinics, FQHCs, etc.) and other health care organizations throughout the United States. For nearly twenty years HBMA has been the billing industry organization recognized for education, advocacy and cooperation in all matters that affect the processing of provider claim-related data, compliance and management services. Our member companies process in excess of 350 Million claims annually and serve virtually every clinical specialty, in every setting, in every state.

Our members include companies with over three thousand employees and dozens of branch offices down to sole practitioners with solo practices as clients. The average member billing company employs approximately thirty, serves 100 or more physicians and processes 40,000 or more claims per month. Some of our members (but far less than half) supply the practice management systems

used by their office-based clients, while others receive information in electronic, as well as paper forms on behalf of

their hospital-based and non-physician clients. As it is with practices handling their own billing, data arrives, moves and leaves by a host of means, not all of it electronic. For over fifteen years, HBMA has worked closely with CMS and other federal agencies, including the OCR, to support the tenets of HIPAA. We have provided comments, testimony, private and public input related to patient privacy as well as offering a wide array of education materials, conference programs, references, announcements and targeted training for our member companies and their employees and clients.

BACKGROUND

HBMA member companies are in the unique position of being both Business Associates and Covered Entities, based on CMS' definitions of each. Our everyday business is the receipt, processing, storage, retrieval and disposition of Protected Health Information (PHI) for millions of patients. We respect the responsibility and gravity that comes with handling and protecting PHI as our members and their employees are patients, too. Our members interact both electronically and via paper, with virtually every insurer, Medicare contractor, Medicaid program and all others involved in reviewing and/or paying (or denying payment) for our clients' patients. However, in every instance our member billing companies are the "down-stream" recipients of information that originated with a health care provider.

We believe strongly in the protection of all patients' private information and in transparency in how patients' PHI is used and disclosed. As organizations responsible for the safe handling and processing of millions of patients' records per day, we are keenly aware of our obligations to our clients and their patients. As business owners, we are also acutely aware of our ever-increasing costs of doing business, even as we and our clients earn less per claim.

As you know, patients have had defined privacy rights under HIPAA for almost a decade. In that time, HBMA members have been prepared to – and have – supplied billing information requested by patients as part of a patient's broader desire to obtain a copy of their data or know how their PHI was distributed and shared. However, because billing companies are not providers and, as such, never have possession of a patient's original medical record, patients must seek their medical record from the provider and the billing information from our member (often via their provider). Our members, despite processing millions of claims annually, report a scant number of requests per year, with many reporting none at all.

TECHNOLOGY

A. Basic Capabilities

In reviewing the NPRM, it appears that one of the underlying assumptions is that existing software is already able to identify when PHI has been accessed, and by whom. In addition, it appears that HHS assumes that the HIPAA "minimum necessary" rules have been incorporated into existing software.

While both capabilities exist within many established hospital software products, less than half of all medical practice products (so-called "practice management" systems) possess either or both of these capabilities. To be sure, some of the most expensive products – mostly developed and sold to medical schools, very large practices and hospital-owned medical groups have these capabilities, as do some "middle market" products, but many software products used by medium and small practices have only one, or neither.

In addition, there are a significant number of specialty-specific software products serving very small niche markets, such as Anesthesiology, EMS/Ambulance, IDTF, ASC, etc. and many of these products lack one or both capabilities. Medical billing companies routinely select from the existing "practice management" marketplace for the systems they use to serve multiple practices.

While it is easy to conceptualize how software might perform those functions, the system "overhead" required to grant selected/limited permission to access certain data, and/or certain patients' data, and/or certain providers' patients, and/or perform selected functions, and/or see selected data, etc., is substantial for server-based and remotely hosted (ASP – Application Service Provider) products. Likewise, the additional data logging and storage requirements to record and store every "touch," along with the identity (log-in) of each user, is considerable, and materially increases the cost to add these capabilities to existing products. Many popular and widely used products have yet to incorporate these features.

HBMA is concerned that the software industry has not yet developed and offered capabilities that meet existing HIPAA expectations, let alone the far more sophisticated requirements contemplated under this proposed rule. It is our belief that the absence of basic HIPAA "features" is a result of economics, as well as user priorities. The pace of change in medical billing software has been breathtaking for over five years, as exemplified by the imminent transition from the 4010A1 transaction standards to 5010, the transition from ICD-9 CM to ICD-10 CM in 2013, the implementation of EMRs by medical practices and the consequent demand for data interfaces and/or integration, to name a few.

B. Electronic Medical Records

The products, vendors, features and marketplace for Electronic Medical Records (EMR) are still in their infancy. Some vendors offer EMR products with an integrated billing capability, whereas many vendors offer either an EMR or a practice management/billing product. Some

of the latter are directly (real-time) interfaced to the customer's EMR, but many are not. As with systems discussed in **A.**, above, some of these products include "minimum necessary" and/or "logging/storing" capabilities, but many have only one, or neither.

Medical practices that have implemented electronic medical record (EMR) systems continue to outsource their billing functions to some of our member companies and some of our members also provide EMR systems, in addition to providing billing and other services. Overwhelmingly, HBMA member companies utilize the same commercial software used by medical practices and hospitals to perform the same functions internally.

As noted by OCR, we, too, are unaware of any EMR product that currently offers a capability for individual users to record the reason a patient's PHI was accessed. It is our belief that such a capability, if developed, would be costly to create, even more costly to implement, and, most importantly, dramatically expensive to operate, once implemented due to the significant time and attention demand that feature would add to the minute-by-minute workflow of a practice, a billing company (or a practice's own billing staff), a clearinghouse, etc.

C. Reason(s) for accessing information

OCR proposes to oblige providers, their Trading Partners and Business Associates to be able to, upon request, supply a patient with information about their PHI that includes the reason why it was accessed. HBMA is unaware of ***any*** system – practice management, EMR, fully integrated system, or hybrid – that currently possesses this capability, nor are we aware of any such system that anticipates or plans to add that capability.

Furthermore, there is no existing classification system; taxonomy; hierarchy; or industry workgroup discussing the development of any system or process by which such reasons could be uniformly classified, recorded and reported. Anecdotally, HBMA has, for over a decade, advocated having a uniform, stable and consistent set of denial codes within the HIPAA Transaction Code Set, without success. We are highly skeptical that an industry-wide, usable and uniform set of "reason codes" could be devised in under five years. And without uniformity, the software industry, providers and their patients, as well as CMS/OCR officials would find operations, management and oversight nearly impossible.

The impact on the workflow of any health care provider could be crippled by this new requirement, even if systems are in place and there is a standardized classification system for access "reasons." For example, in the course of a simple office visit, the patient of an office-based practice would have their PHI "accessed" – requiring the manual selection and manual entry of a "reason code" – no less than 19 times:

1) Receptionist answers initial call and transfers the call to the scheduling employee;
2) The scheduler makes the appointment;

3) The scheduler [or another employee] verifies the patient's coverage;
4) Employee reviews schedule for appointment reminder and sends reminder or schedules/makes reminder call;
5) Employee reviews schedule and retrieves paper chart and/or generates an encounter form for next-day appointments (this function might be assigned to multiple employees, creating multiple accesses);
6) Patient arrives for appointment and is greeted by receptionist, directed to waiting area;
7) Employee greets patient and escorts to exam room;
8) Medical Assistant interviews patient [reason for visit], checks vital signs, etc.;
9) Nurse interviews and/or screens patient;
10) Physician interviews and examines patient;
11) Lab tech draws blood, obtains urine sample, etc.;
12) Physician interprets CLIA lab tests and enters results in chart;
13) X-Ray technician performs imaging study and develops/transfers image to physician;
14) Physician interprets image and enters results in chart;
15) Physician verifies and/or renews and/or writes prescription(s);
16) Patient returns to reception desk to check out;
17) Patient is referred to another physician or specialist for further diagnosis and/or treatment;
18) Referral request entered into chart;
19) Patient schedules next appointment.

Each of those 19 "touches" would add another interruption to the workflow and require a separate interaction with the practice's system – even if there is no other reason to access the system at that juncture. Hospital inpatients would have – literally – hundreds of "accesses" per day.

Other common scenarios, such as patients admitted to a hospital for surgery or obstetric care, patients taken to an Emergency Department, referred for an MRI in a hospital, referred for radiation therapy in a treatment center, etc., will create a multitude of PHI "touches" and, unlike the office practice, will trigger PHI "reasons" within MULTIPLE organizations' systems; e.g. hospital system, practice system, departmental system(s), Radiation Therapy Center, etc.

Patients who return repeatedly for treatment, such as for Physical Therapy, Cardiac Rehab, Infusion Therapy, Chemotherapy, Occupational Therapy, etc. could generate hundreds of PHI "accesses" per week. A patient seeking an accounting of their PHI, must today, as well as the future, make separate requests to each organization. However, the NPRM requirement that the "reason" be part of that accounting would cascade throughout that entire list and produce massive amounts of work and cost for the individual providers. HBMA is concerned that this significant cost would not be justified by the minimal amount of valuable information a patient might obtain through this process.

In addition to all of the above, if a billing company handles the billing for any or some of the providers – or several companies bill for several providers (billing is often outsourced by clinical specialty) the companies' system will have multiple PHI "reasons" to record as data

arrives, is entered, is coded, is processed, is billed, payment(s) are posted, non-payment(s) [denials, pended claim, etc.] are posted, calls to insurers are made, calls from patients are received, delinquent balances are transferred to a collection agency, etc. And, since 95% of claims are submitted via a clearinghouse, there would be additional PHI "accesses" to be recorded throughout that complex process involving multiple entities.

HBMA believes that this extraordinary and extreme amount of additional work and information will provide the intended beneficiary – the patient – little or no additional protection or insight regarding how their PHI was used and/or protected. Further, we believe that little, if any, meaningful information will be created or made available to patients as a result of the rules proposed. As several of our members have observed, this NPRM represents a "solution in search of a problem."

ADDITIONAL BURDENS

To the extent that software systems cannot fulfill all of the proposed access and reporting requirements, health care providers and their vendors might be obliged to perform these functions manually. This will cause either universal non-compliance or will bring workflow and productivity to a near standstill, the latter at enormous new costs to providers. Although the NRPM describes its proposals in terms of recording access and reasons as a technology function, we are concerned that providers who would be unable to comply via technology might be obligated to comply manually. The resources, labor and related costs of such an obligation would, in our opinion, be operationally catastrophic for providers, hospitals, billing companies and all others with PHI handling responsibilities. In addition, the time added to patient interactions would be tedious and disruptive, reducing the efficiency of care and prolonging patients' care.

COMPLIANCE

HBMA's membership includes some companies with full-time Compliance Officers, although due to each organization's size, most companies address compliance via part-time responsibility of an employee with other duties. These full-time or part-time positions have dual responsibility for overall compliance (coding, billing, OSHA, PCI, etc.) as well as HIPAA compliance. In recent years, hospitals and other large healthcare systems have found it necessary to add full time positions (Privacy Officers) to address the growing regulatory requirements under HIPAA and HITECH; however, billing companies and medical practices alike are simply unable to justify or fund new positions dedicated to HIPAA and patient privacy. The challenges associated with implementation of the various HIPAA and HITECH regulations have already created an enormous strain on the limited resources of medical practices and billing companies.

We are concerned that the proposed additional administrative responsibilities will be a distraction to these compliance professionals at a time of increased enforcement activity associated with the

identification of fraud, waste and abuse in healthcare. These obligations have already heavily taxed the capacity of these individuals. If billing companies and the medical practices that they support are obligated to comply with the proposed new rules, we are concerned that this will simply lead to "nullification," as a new set of regulatory requirements for which they have no capacity to comply; which is a right rarely, if ever exercised by patients; and which is perceived to be of no meaningful value to the patient, even if provided.

RECOMMENDATIONS

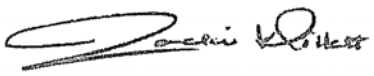
1. HBMA recommends that the proposed rules be withdrawn. Perhaps in five years, after practice management and EMR systems have evolved further and affordable, more sophisticated capabilities can be incorporated into those systems, the proposed capabilities may begin to appear and/or have a likely chance of being successfully developed and delivered.

2. If OCR remains interested in assuring access to this additional data about patients' PHI, we recommend an initiative to develop a classification/coding protocol for "reasons." This development would logically be initiated through existing industry standards organizations, such as WEDI, ANSI X12, SNIP, etc. Based on past history, this process will take three to five years unless it is expedited as a high priority.

3. In the event that these regulations are to be implemented, we strongly recommend that the implementation be deferred until at least 2015 or later in order to allow time for the highly complex and almost certain negative economic impact of the transition to 5010 and ICD-10 CM.

HBMA appreciates the opportunity to respond to this NPRM and remains interested and available to work with HHS and/or OCR should you seek to modify or further research the practicality of the proposed rules or new or substitute rules.

Respectfully submitted,



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