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FHA 242 Hospital Mortgage Insurance: An Alternative to Traditional Commercial Credit Enhancements

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I. Introduction

Under traditional tax-exempt bond financing arrangements, nonprofit and municipal hospitals will frequently obtain a credit enhancement policy, such as municipal bond insurance or a bank letter of credit. The purpose of credit enhancement is to shift the ultimate risk of repayment from the borrowing hospital to the bank or bond insurer. This means that the bondholder will rely upon the credit rating of the bank or bond insurer resulting in bonds that are easier to market, lower interest rates and a reduction of the hospital's cost of capital.

Recent health system bankruptcies coupled with a decrease in federal reimbursement rates paid to hospitals has reduced the ability of hospitals to obtain traditional commercial credit enhancement. The difficulty in obtaining credit enhancements has happened at a time when there has been a corresponding increase in the market demand for credit-supported debt. Consequently, there has been a dramatic increase in the cost to hospitals in obtaining credit enhancement. In other words, as banks and bond insurers perceive increased default risk (*i.e.,* a greater likelihood that they will have to make a debt service payment), they charge more for the guarantees they provide. Consequently, many hospitals now believe their only alternatives are to issue bonds supported solely by their own general obligation without credit enhancement at punitive interest rates, or pay significantly more for any commercial credit enhancement that may be available. In either case, the cost of borrowing has increased. Worse, for many small hospitals, such as critical access hospitals, debt financing simply may no longer be an option.

This article describes an alternative credit enhancement vehicle available to most hospitals, which allows hospitals to obtain mortgage insurance through the United States government to securitize and credit enhance their bond issues. The product is FHA 242 Hospital Mortgage Insurance (FHA Mortgage Insurance). Section 242 of the National Housing Act[1] authorizes the Federal Housing Administration (FHA), an agency within the Department of Housing and Urban Development (HUD), to help hospitals obtain affordable financing for capital projects by means of FHA Mortgage Insurance. As an alternative to commercial credit enhancements, FHA insured mortgages are backed by the full faith and credit of the United States government which will enable the borrowing hospital to obtain up to a AAA debt rating on either taxable or tax-exempt bond issues. One of the most appealing terms of the FHA 242 Hospital Mortgage Insurance Program (the Program) is its non-recourse, single borrower, general obligation security pledge. Therefore, if the borrowing hospital is a member of a larger health system, the debt remains an obligation solely of the borrowing entity and does not encumber in any way the revenues of the other affiliates in the health system. Therefore, the health system's overall credit rating is unaffected.

The impact of the Program is to facilitate debt financing of hospital construction projects

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for many hospitals that have no alternative cost-effective financing means. For example, a non-rated nonprofit hospital seeking to access tax-exempt financing without credit enhancement will borrow at rates of at least 9% due to its modest financial strength and the inherent risks associated with the construction and start-up of a new or replacement facility. With FHA Mortgage Insurance immunizing the bondholders from the risk of default by the hospital, the interest rate will drop to 5.5%, or an effective 6.25% after taking into account the loan servicing fees and the mortgage insurance premium. As a result, the borrowing hospital will have more funds available to divert to its healthcare purposes rather than expending its funds on debt service.

The benefits of FHA Mortgage Insurance are even more striking for a community facility or critical access hospital where the Program may provide the only financing option. For these hospitals, the borrowing rate without credit enhancement could be as high as 10%, and this assumes there is even investor demand for the bonds, which in this market environment is unlikely. Moreover, because critical access hospitals receive Medicare reimbursement under a cost based system, rather than the national Prospective Payment System, their operating profits are bolstered and borrowing capacity increased. In fact, to expand its universe of critical access hospitals for the Program, HUD permits mortgage bankers to recast the financials utilizing a cost based reimbursement methodology of critical access hospitals for the three-year period prior to their critical access hospital conversion date. This serves to improve the financial results when measuring the hospital's historical performance against the Program's minimum threshold financial requirements. Finally, as discussed below, the critical access hospital is exempt from HUD-mandated certificate of need (CON) requirements.

In short, the Program significantly increases access to capital markets, marketedly decreases borrowing rates, requires reasonable financial eligibility requirements and standard debt covenants in the form of a single-borrower non-recourse loan, and does it all under the auspices of a program whose mission of promoting health is identical to the borrowing hospital's mission. The remainder of this article will describe some of the terms and conditions of FHA Mortgage Insurance, the HUD application process and certain state CON requirements.

II. Terms and Conditions

A. Borrower

Regardless of whether it is large or small, urban or rural, nonprofit or proprietary, a hospital can qualify under the Program if it is an acute care hospital with no more than 50% of its revenues or patient days attributable to convalescent care, drug and alcohol dependency, epilepsy, tuberculosis, or mental health.[2] In addition, a hospital must expect no more than 50% of its revenues over the life of the project plus two years to come from such sources. As security for the mortgage insurance, the hospital must have fee simple title to the mortgaged property (or in certain cases be a lessee under a long-term lease).

B. Use of Mortgage Proceeds

Mortgage proceeds may be used for construction financing, modernization, remodeling, capital equipment, expansion, acquisition or refinancing. If mortgage proceeds are used for acquisition or refinancing, a minimum of 20% of the proceeds must be used for facility renovation, rehabilitation or the purchase of new equipment (but no more than half of the 20% may be used for equipment upgrades).

C. Term

The term of the mortgage is the construction period plus 25 years.

D. Amount

For new construction projects, the mortgage amount is 90% of the total project costs, including equipment, furnishings and land value. For rehabilitation or refinancing, the maximum insurable amount can be up to 100% of the estimated current costs of rehabilitation provided such amount plus any existing debt does not exceed 90% of the value of the facility after completion of the project. This value is usually the net book value of the plant, property and equipment.

E. Security

The security is provided by a first mortgage lien on the entire hospital, including all appurtenances such as parking lots, garages, and medical office buildings (or in certain cases the assignment of a long-term lease).

F. Recourse

FHA has recourse only against the assets of the borrowing hospital but not the assets of a larger system or obligated group.

G. Financing Methods

Taxable or tax-exempt bond financing may be used.

H. Additional Financing

Additional financing is permitted (especially to cover the 10% not eligible for the HUD insurance), but revenues or a second mortgage of the property must secure such financing and the security cannot include any foreclosure rights.

I. Minimum Financial Requirements

Over the prior three fiscal years, the hospital should have an average operating margin equal to or greater than 0.00% and average debt service coverage equal to or greater than 1.25x. HUD can waive or modify these requirements. For new construction projects, HUD will evaluate proforma financials against these criteria. Critical access hospitals have less strenuous requirements.

J. Mortgage Covenants

Standard covenants regarding additional debt, transfer of assets, minimum debt service, etc., will apply but are generally kept to a minimum.

K. FHA Fees

There is an FHA Application Fee of 0.15% of the mortgage amount due at the time of the submission by the FHA mortgage banker of the FHA Mortgage Insurance application. An FHA Commitment Fee of 0.15% is due upon issuance of the HUD Firm Mortgage

Insurance Commitment. At mortgage closing, there is an FHA Inspection Fee of 0.5% of the mortgage amount. Additionally, a mortgage insurance premium of 0.5% times the number of years in the construction period is capitalized at closing. On an annual basis, the mortgage insurance premium of 0.5% of the outstanding mortgage amount is paid as part of the monthly mortgage payments.

L. Third Party Fees

Depending on the project, other fees normally associated with bond issues will apply (borrower's counsel, bond counsel, and placement and other fees for brokers, mortgage bankers, investment bankers and financial consultants). HUD may permit these costs to be capitalized at closing, subject to the 5% limitation imposed by the IRS on private activity use.

M. Escrows

The hospital borrower is required to establish a Mortgage Reserve Fund equal to one year's debt service within five years, and two year's debt service within ten years. Standard escrows for taxes and insurance, if applicable, will generally be required. In addition, a working capital escrow may be required (especially for new projects), either through cash postings or letters of credit, until the project becomes self-sustaining.

III. HUD Application Process

If all goes well, the FHA Mortgage Insurance process can take six to nine months from engagement of the mortgage banker through mortgage and loan closing and disbursement of loan proceeds. Tax-exempt bond issues can add additional time, as can regulatory requirements such as Hart-Scott-Rodino filings with the Department of Justice/ Federal Trade Commis-sion. The process begins with the hospital determining the need for a new or replacement facility and assessing its ability to pay the requisite debt service. The hospital must select one of a handful of qualified FHA-licensed mortgage banking firms. The firm is necessary to navigate the hospital through the application process, representing and advocating for the hospital, while at the same time acting in consort as an underwriter for HUD and assuring HUD that extending mortgage insurance coverage to the hospital is an acceptable credit risk.

This process commences with an informal meeting with HUD representatives where HUD identifies any significant weaknesses in the proposed project or the hospital's ability to meet the minimum financial underwriting requirements. If HUD approves the project, the mortgage banker submits an initial pre-application to HUD. The contents of the pre-application are generally proprietary and vary based upon the recommendation of the mortgage banker, but can include, among other things, a project description and budget, architectural drawings and plans, information about the borrowing hospital, historical and pro forma financials and utilization statistics, market and demographic data, and any CON approval if required by the state.

At the submission of the pre-application, the key advisors meet with HUD to discuss the pre-application and answer questions. This team, directed by the mortgage banker, would include hospital representatives (board and management), the owner's representative, the construction manager, the architect, borrower's counsel, and any investment bankers and financial advisors. Assuming HUD gives the go ahead, the remaining months of the process consist of continued communication with HUD, the Department of Health and Human Services (HHS) and the Office of Engineering Services (OES) (which oversees the design and construction), answering questions and providing additional information and clarification, HUD and HHS site inspections, and eventually receiving the firm commitment from HUD. During this time, the hospital is also beginning the bond financing stage (preparation of necessary bond and legal documents) and, thereafter, completing its bond process (presentation to bond issuing authority, pricing of bonds, sale of bonds by investment bank, etc.) and any other legal matters such as antitrust approvals. The mortgage insurance and bonds are closed concurrently and proceeds become available for construction draws and construction commences. OES continues to oversee the construction phase through completion.

IV. State Certificate of Need Process

For states that have a CON process, the project is required to comply with state CON requirements and a copy of the CON approval letter must accompany the final application to HUD. For states that do not have a CON process, borrower's counsel must work with HUD and a state agency (such as the department of health, bond issuing authority or economic development authority) to develop an alternative process whereby the state commissions and pays for a feasibility study that: (1) is prepared in accordance with the principles established by the American Institute of Certified Public Accountants; and (2) assesses, on a market-wide basis, the impact of the proposed hospital on, and its relationship to, other healthcare facilities and services, the percentage of excess beds, demographic projections, alternative healthcare delivery systems, and the reimbursement structure of the hospital. The consultant must (1) be selected by the state and approved by HUD; (2) demonstrate it has experience within the prior three years preparing such a study; (3) demonstrate that it presently has the resources and capacity (in terms of experienced personnel and information systems) that would enable it to conduct the study in accordance with HUD requirements; and (4) have no conflicts of interest with the hospital borrower or any of the lenders.

The state can (and probably will) require the hospital applicant to reimburse it for the cost of the feasibility study. In addition, while a favorable study of need and feasibility is desirable, if not necessary, it is only a starting point for HUD's analysis and not an automatic indication that HUD will approve an application. HUD and DHHS will review the project based in part upon the

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study but also in conjunction with its own internal feasibility study. For states participating in the process for the first time, HUD will generally require evidence that the state has the authority (statutory, regulatory or otherwise) to commission and pay for the study. This is usually done through a legal opinion issued by an attorney for the state (e.g., the office of the state attorney general or counsel for the state agency with which the borrowing hospital is working). An important exception to all these feasibility study requirements is for critical access hospitals. However, while critical access hospitals (designated as such by the state and DHHS) are not required under the Program to obtain a feasibility study in order to qualify for the FHA Mortgage Insurance, in many cases it is strongly encouraged.

In addition to the above federal statutory requirements, the state may have additional requirements. For example, some states will select the consultant requested by the applicant hospital while others bid out the service. Other states require the hospital applicant to present several names, and give a ranking of the options, but the state makes the final selection. In some states, the department of health will commission the study, while in other states it may be an economic development department or the bond issuing authority. In non-CON states that do not have an established system for selecting a consultant (*e.g.,* a state in which no hospital has previously secured FHA Mortgage Insurance), borrower's counsel will have to work with the appropriate state agency to develop the process the state will use. Generally, the attorney and state agency will have to create this process from scratch but will have input from HUD and can model procedures that other non-CON states utilize.

V. Conclusion

Many hospitals, from large health systems to a small 25-bed critical access hospital, can access low-cost debt financing by obtaining affordable credit enhancement through the Program, a more desirable and less expensive alternative to often unreceptive commercial credit enhancers. While this article has provided an overview of the FHA Mortgage Insurance process, there remain additional details that need to be addressed in each transaction. These include: HUD requirements governing the format and content of the feasibility study; the regulatory agreements between the hospital and HUD; the mandated third-party reports needed in the underwriting process; the trust agreement governing the Mortgage Reserve Fund; the formulation and negotiation with HUD of specific hospital loan and financial covenants; the generation of cash flow analyses for the mortgage, the escrow funds and the bonds; and the HUD-specific requirements of all members of the working group including the owner's representative, architect and construction manager. Through the coordination of professionals experienced in healthcare, real estate, municipal finance, law, construction and design, and most importantly FHA regulations, a hospital can be led through this process with surprising efficiency.

Endnotes

1 12 U.S.C. 1701, *et seq*.

2 12 U.S.C. 1715z-7(b)(1). Similarly under the Program, nursing homes, assisted living centers, independent living centers and intermediate care facilities can also qualify for FHA Mortgage Insurance. 12 U.S.C. 1715w.

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Greetings!

Hospitals and health systems continue to face challenges in the delivery of healthcare services to the communities they serve. At the same time, various government agencies refine and release regulations which affect the delivery of care and the status of many of these health care providers as nonprofit entities.

This edition of the *Hospitals and Health Systems Newsletter* touches upon many current issues of interest for SISLC members. Clinical research, and the effect such research has on test study participants, continues to be an area of focus for medical research centers. Patient protection, always a central focus of such programs, continues to be in the spotlight as governmental agencies promulgate rules that refine the conditions under which clinical research must take place. Also contributing to the increased scrutiny of such initiatives is the ever-present possibility of participant-initiated litigation.

Governmental agencies have promulgated and revised rules that will affect the operations of hospitals and health systems. The Internal Revenue Service issued in final form the intermediate sanctions regulations, these regulations have clarified and highlighted the importance of documenting the fair market value of transactions and identifying, early on, those individuals who will be subject to the limitations of those rules. Nonetheless, until there is a history of guidance that applies those rules to actual health system operations, there will be a need for guidance and caution with respect to operations.

HIPAA and EMTALA rules continue to develop in ways that will impact hospital operations. This edition of the Newsletter focuses upon the issues raised by the Notice of Proposed Rulemaking and its impact upon HIPAA. Additionally, the EMTALA rule modifications will impact hospitals and the delivery of critical care.

Next year the Hospitals and Health Systems SISLC will launch new programs for members that are intended to guide our members through the operational issues which we face in providing services to our communities. We will increase communications through our listserve as well as through teleconferences and other projects. As always, we solicit your input for ideas on how the SISLC can continue to serve you.

Best Wishes for a Happy Summer!

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SISLCs Get A New Name

Did you notice that we've changed our name from SISLC to Practice Group? Feedback from our members indicates that this designation more accurately identifies who we are and what we do. We haven't changed our objectives though-our Group is still composed of members who want to increase their level of expertise in and knowledge of health law issues, grow professionally, gain valuable leadership experience, and network with other health lawyers from across the country. So start looking for us on the web, in publications, at programs, etc. under our new name: **Practice Groups**

Brief Review of the Final Rule Implementing a National Medicare Fee Schedule for Ambulance Service

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I. Introduction

On February 27, 2002, the Centers for Medicare and Medicaid Services (CMS) published a final rule (Final Rule) implementing a national Medicare Fee Schedule for payment of ambulance services.[1] The Final Rule contains significant changes to the reimbursement methodologies previously used by Part A Fiscal Intermediaries and Part B Carriers when processing provider and supplier claims[2] for ambulance service. Since it is believed that, on average, at least Medicare covers 50% of ambulance transports in the U.S.,[3] these changes will have a sweeping impact on the entities that provide the service. In response to this rule, hospitals that own ambulance providers will have to implement major changes in their own operations to ensure that they obtain and document the information necessary to receive the appropriate reimbursement. In addition, many independent ambulance suppliers benchmark the fees in their service contracts to the applicable Medicare rate. Hospitals that contract with such independent suppliers for the provision of ambulance service will need to be aware of the fee schedule's service levels and payment provisions in order to appropriately pay for their contracted ambulance services.

II. Background and History

Section 1861(s)(7) of the Social Security Act (Act) requires that Medicare Part B provide coverage for medically necessary ambulance service.[4] Section 1834(l)(1) of the Act required that CMS establish a fee schedule for ambulance service via negotiated rulemaking. Previously, ambulance service providers and suppliers had been reimbursed on a reasonable charge or reasonable cost basis.[5] In 1999, CMS published a solicitation for participation in a negotiated rulemaking process for ambulance service[6] and, in 2002, CMS published a final rule without the opportunity for public comment[7], which was implemented on April 1, 2002. A brief summary of each change created by the Final Rule follows.

III. Five (5) Year Phase-in of the New Fee Schedule

CMS recognized that implementation of the National Fee Schedule (Fee Schedule) would have a significant financial impact on ambulance service suppliers and providers. The Final Rule includes a five (5) year phased in implementation schedule.[8] The phase-in will be accomplished by reimbursing suppliers a specified percentage of the fee schedule allowable amount, plus a specified percentage of the former payment the supplier would have been entitled to.[9] It is important to note the first quarter of 2002 is ignored by CMS; the first year of the Fee Schedule's implementation is composed of only nine (9) months.[10]

IV. Mandatory Assignment

Section 1834(l)(6) of the Act requires that all payments for ambulance service must be made on an assignment-related basis. The Final Rule thus provides that "[e]ffective with implementation of the ambulance fee schedule ... all payments made for ambulance service are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts."[11] CMS' responses to public comments on the proposed rule indicate that assignment is mandatory even where Medicare is the secondary payer.[12]

V. New Levels of Service Have Been Identified and Assigned New HCFA Common Procedural Coding System (HCPCS) Codes

The Final Rule establishes nationally uniform levels of ambulance service. The levels of service are first divided by two differing transport modes—by air, or by ground.[13] Each mode is then subdivided by the level of care required by the patient.

A. Air Transport

Air ambulance transportation is divided into two categories: Fixed Wing (FW) and Rotary Wing (RW, *i.e.*, helicopter). Air ambulance transport is covered when "the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by land vehicle, or great distances or other obstacles (*e.g.*, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either basic life support (BLS) or advanced life support (ALS) ground ambulance.[14] The aircraft used to provide the service must be certified as either an FW Air Ambulance or an RW Air Ambulance in order for the provider or supplier to receive Medicare reimbursement.[15] Loaded miles to the closest appropriate facility[16] are paid separately, on a per-mile basis.[17]

B. Ground Transport

Ground transport is divided into three categories: BLS, ALS and Specialty Care Transport (SCT). BLS ground ambulance transport is generally provided where the patient requires no advanced care enroute, but rather cannot safely be transported by other means. The Final Rule defines BLS ground ambulance transportation as "transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in accordance with state and local laws as an emergency

medical technician-basic (EMT-Basic)."[18] BLS ambulance transportation is the most common form of ambulance transport provided in the U.S. ALS ground ambulance transport is generally provided when the patient requires BLS ambulance transportation plus advanced care en route, such as the administration of ALS medications, or the provision of certain ALS procedures. The Final Rule requires that ALS provider (EMT-Paramedic) be certified as required by state or local law.[19]

The Final Rule defines SCT as "interfacility[20] transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and service, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training."[21]

VI. Emergency Response Modifier Change

In the past, increased reimbursement for emergency responses has been obtained based on the condition of the patient as discovered upon the ambulance's arrival. In contrast to this practice, the Final Rule provides increased emergency response reimbursement based on "the additional overhead cost of maintaining the resources required to respond immediately to a call and not for the cost of furnishing a certain level of service to the beneficiary."[22] Therefore, effective April 1, 2002, an emergency response is defined as "responding immediately at the BLS or ALS-1 level of service to a 911 call or the equivalent in areas without a 911 system."[23] An immediate response is "one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the call."[24]

VII. Elimination of Multiple Billing Methods

Previously, CMS permitted providers to bill by one of four (4) different methods. Under the final rule, all suppliers must bill by a single, national method (a single, all-inclusive fee for transportation and supplies, plus a separate, per-mile fee). During the transition period, providers that previously billed under methods that allowed separate charges for supplies may continue to do so. However, the reimbursement for supplies will be reduced each year during the transition until the end of the transition period, at which time separate reimbursement for supplies will be eliminated, and payment for these items will be considered included in the base rate.[25]

VIII. Reasonable Cost Reimbursement for Providers Has Been Eliminated

Ambulance providers owned by hospitals bill the appropriate Part A Fiscal Intermediary for their services. In the past, these services were reimbursed on a reasonable cost basis.[26] Year to year increases in this reimbursement were recently subject to a statutory inflation factor cap.[27] After April 1, 2002, ambulance providers will receive reimbursement based on a "blending" of the amount payable under the old system, and the amount payable under the Final Rule.[28] The relative percentages of the blend are identical to those utilized by the Part B transition.[29] The mandatory assignment rule is also imposed upon providers.[30]

IX. New Physician Certification Statement Requirements for Non-Emergency Ambulance Service ***(Including a National Definition of the Term "Bed-Confined")***

CMS imposes special requirements for suppliers that provide non-emergency ambulance service. Providers have always been required to obtain a certificate attesting to the medical necessity of the ambulance service for which they bill. Suppliers have been subject to a series of program memoranda regarding certification requirements for ambulance service.

The Final Rule implements a national policy regarding suppliers' responsibilities to obtain written certifications attesting to medical necessity prior to submitting claims for certain incidents of non-emergency ambulance service. Of course, the supplier must maintain patient care documentation demonstrating that ambulance service is medically necessary. If such documentation is not available (whether because the ambulance crew did not complete the documentation, or because medical necessity was not present), the supplier should not submit a claim for reimbursement to a federal healthcare program.

A. Non-Emergency, Scheduled, Repetitive Ambulance Service

Prior to the provision of scheduled, repetitive non-emergency BLS ambulance service,[31] the supplier must obtain "a written order from the beneficiary's attending physician certifying that the medical necessity requirements of [42 CFR § 410.40(d)(1)] are met."[32] If the supplier does not obtain the required certification, it may not submit a claim for the service. The supplier is not required to submit a copy of the certification with the claim; however, it must maintain the certification "on file, and upon request, present it to the [Part B] contractor."[33]

B. Non-Emergency, Unscheduled, or Scheduled but Non-Repetitive Ambulance Service

If unscheduled, or scheduled non-repetitive non-emergency BLS ambulance service is provided to "a resident of a facility who is under the care of a physician," the ambulance supplier must obtain the physician certification statement (PCS) from the beneficiary's attending physician "within 48 hours after the transport."[34] However, CMS realizes that it may be difficult for the supplier to locate the patient's physician, and obtain the necessary PCS within forty-eight (48) hours. The Final Rule provides alternative mechanisms to comply with this requirement.

If the provider or supplier is unable to obtain a signed PCS from the patient's physician, they may attempt to obtain it from a:

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1. Physician Assistant;
2. Nurse Practitioner;
3. Clinical Nurse Specialist;
4. Registered Nurse; or,
5. Discharge Planner

who has "personal knowledge of the beneficiary's condition at the time the ambulance transportation is ordered or the service is furnished. This individual must be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported."[35] The individual must be licensed pursuant to Medicare regulations and applicable state licensure laws.[36]

In the event that the ambulance supplier cannot obtain the required certification within 21 calendar days after the date of the service, the supplier can document attempts to obtain the certification, and then submit the claim.[37] Such documentation can take the form of a "signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other [approved] individual."[38]

C. National Definition of Bed-Confined

The various Part B carriers have maintained separate definitions for the term bed-confined as used to support medical necessity for ambulance service. Urban lore tells of one carrier that indicated that bed-confined was a condition, "such that if a patient were suffering it, and their bed were to catch fire, absent assistance, the patient would surely burn to death." The Final Rule implements a national definition of the term bed-confined. For purposes of determining medical necessity for ambulance transport, bed-confined means:

1. The beneficiary is unable to get up from bed without assistance;
2. The beneficiary is unable to ambulate; and,
3. The beneficiary is unable to sit in a chair or wheelchair.[39]

The Final Rule also indicates that bed confinement is not, in and of itself, the sole criterion in determining medical necessity for ambulance transportation. Rather, it is one factor to be considered. The beneficiary must be bed-confined and it must be documented that their condition "is such that other methods of transportation are contraindicated."[40]

X. All Ground Ambulance Mileage Charges Paid at One Rate

In the past, Medicare's reimbursement for mileage charges varied based on the level of service provided. The Final Rule establishes a single, unified fee for ground ambulance mileage.[41] Payment for this item, on a per-mile basis, will be phased in along with the rest of the National Fee Schedule.

XI. Location-Based Payment Modification

Prior to the Fee Schedule's implementation, each Part B Carrier maintained different reimbursement schedules for ambulance service. The Final Rule provides that the location of service payment modifiers will be based on the point of pickup, as defined by the zip code of the street address where the patient was placed in the ambulance.[42] The comments indicate that this was adopted to prevent, in part, "the relative ease of moving the location of the company or garage to achieve higher payment."[43]

The Final Rule includes two "point of pickup" payment modifiers. The first is the Geographic Adjustment Factor (GAF). The GAF applies the practice expense (PE) portion of the geographic practice cost index (GPCI) from the Medicare physician fee schedule as applied to a percentage of the base rate.[44] The applicable GAF is the GPCI PE that applies to the zip code at the point of pickup.[45] The GAF is applied to 70% of the ground ambulance service rate.[46] For air ambulance services, the GAF is applied to 50% of the base rate.[47]

The second location-based modifier is the Rural Adjustment Factor (RAF). The RAF is defined as "an adjustment applied to the base payment rate when the point of pickup is located in a rural area."[48] The RAF is applied to the mileage rate for ground ambulance service, when the point of pickup is located in a rural area.[49] The mileage rate is increased by 50% for the first seventeen miles, and by 25% for miles eighteen to fifty. For air ambulance service, the total payment (base plus mileage) is increased by 50%.[50]

XII. New Payment Policies for Multiple Patients in One Ambulance

In the past, there was no coherent national Medicare policy on billing for multiple trauma transports. The Final Rule now provides clear direction by stipulating that when transporting two patients in the same ambulance, the payment allowance for the Medicare beneficiary (or for each of them, if both are Medicare beneficiaries) is 75% of the applicable base rate (modified by any location-based modifiers) in respect of the level of service provided to the beneficiary, plus 50% of the applicable mileage payment allowance.[51] If three (3) or more patients are simultaneously transported in the same ambulance, the payment allowance is decreased to 60% of the applicable base rate, per Medicare beneficiary transported, plus the applicable mileage allowance divided by the number of patients on board, per beneficiary.[52]

XIII. Elimination of Medicare Payment for ALS Mandated Responses

In the past, Medicare paid for BLS ambulance service at the higher ALS rate, when the supplier was mandated by local ordinance to provide only ALS ambulance service in the jurisdiction. The Final

Rule eliminates payment for these ALS mandated services.[53] Rather, the Fee Schedule will only reimburse the level of service actually provided. In order to mitigate the effect of this change on ambulance suppliers located in ALS mandate jurisdictions, payment for ALS mandated services will be phased out in steps, in the same manner as the Fee Schedule will be implemented.[54]

XIV. Conclusion

Implementation of the Fee Schedule will affect many hospitals, and nearly every ambulance supplier and provider in the U.S. Suppliers and providers should review their compliance plans in view of the guidance contained in the Final Rule. It is likely that Part A Fiscal Intermediaries and Part B Carriers will have difficulty implementing the many changes contained in the Final Rule. It will be incumbent upon providers and suppliers to make certain that they identify any overpayments received, and to promptly refund it. It is also important to ensure that providers and suppliers are appropriately reimbursed, and to request additional sums if claims are incorrectly underpaid. Providers and suppliers may also request interest if payments are significantly delayed. In any event, implementation of the National Fee Schedule will help Fiscal Intermediaries and Carriers standardize their procedures and will assist CMS to resolve Carrier/Provider disputes in an efficient manner.

Endnotes

1 67 FR 9100-9135, amending 42 CFR Parts 410 and 414.

2 When claims are submitted to Part A by hospital owned ambulance services, CMS refers to the ambulance service as a "Provider;" when submitted by independent services to Part B, CMS refers to the ambulance service as a "Supplier."

3 "Medicare patients compris[e] 50% of total transports for our industry on average" American Ambulance Association Past President Mark Meijer's Testimony, Senate Hearing on Medicare Ambulance Payment Policies - 11/15/01.

4 42 U.S.C. 1395(x).

5 Reasonable cost for Providers; Reasonable charge for Suppliers. 67 FR 9102.

6 64 FR 3474.

7 The February 27 rule indicated that CMS would only accept comments regarding: (a) Cost reimbursement for ambulance services furnished by certain critical access hospitals, and (b) certain technical issues regarding reimbursement for ambulance mileage expenses.

8 42 CFR §414.615

9 The fee schedule will be completely phased in by Fiscal Year 2006. *Id.*

10 April 1, 2002-December 31, 2002. All other "Fee Schedule" years are full calendar years.

11 42 CFR § 414.610.

12 67 FR 9112.

13 The term "ground" includes ambulance transportation by land and by water (*i.e.*, boat). 67 FR 9105.

14 67 FR 9106.

15 42 CFR § 414.605

16 Medicare only pays for medically necessary ambulance transportation when the destination is the closest appropriate facility. In general, the closest appropriate facility is the nearest licensed acute-care hospital that has the capacity to provide the care required by the patient. If a beneficiary wishes to be transported to a more distant facility (for any reason, including proximity to the patient's home, the presence of a preferred physician, the reputation of the more distant facility, etc.), then the beneficiary may enter into an agreement with the ambulance provider to pay "out of pocket" for the additional mileage charges. 67 FR 9115.

17 Ambulance mileage rates may be subject to a "rural" modifier. The details of this rural modifier will be discussed *infra.*

18 42 CFR § 414.605.

19 "An individual trained to the level of emergency medical technician-intermediate (EMT-Intermediate) or emergency medical technician paramedic (EMT-Paramedic) ... in accordance with State and local laws." *Id.*

20 Ground transports to/from a landing zone before/after air ambulance transport are also included in the definition of SCT, provided that the ground transport begins or ends at a facility. *Id.*

21 42 CFR § 414.605.

22 67 FR 9128.

23 42 CFR § 414.605.

24 *Id.*

25 67 FR 9107.

26 67 FR 9121.

27 *Id.*, discussing Section 4531 of the Balanced Budget Act of 1997.

28 Pursuant to Section 205 of the Benefits Improvement and Protection Act of 2000, (BIPA) reasonable cost reimbursement was preserved for Critical Access Hospitals (or entities owned or operated by Critical Access Hospitals) that provide ambulance service if there is no other ambulance provider or supplier within a 35-mile drive.

29 *See infra* for an in depth discussion of the Part B supplier transition schedule.

30 *Id.*

31 But in no case more than sixty (60) days before the date of service. 42 CFR § 410.40(d)(2).

32 *Id.*

[33] 42 CFR § 410.40(d)(3)(v).

[34] 42 CFR § 410.40(d)(3)(i).

[35] 42 CFR § 410.40(d)(3)(iii).

[36] *Id.*

[37] 42 CFR § 410.40(d)(3)(iv).

[38] *Id.*

[39] 42 CFR § 410.40(d)(1).

[40] *Id.*

[41] "Rural" miles are subject to a modifier that will be discussed *infra.*

[42] 42 CFR § 414.605.

[43] 67 FR 9109.

[44] 42 CFR § 414.605.

[45] 67 FR 9109.

[46] 42 CFR § 414.610(c)(4).

[47] *Id.*

[48] 42 CFR §410.605.

[49] Rural area means "an area located outside a Metropolitan Statistical Area (MSA) or a New England County Metropolitan Area (NECMA) or an area within an MSA that is identified as rural by the Goldsmith modification." 42 CFR § 414.605. Goldsmith modification means "the recognition of rural areas within certain Standard Metropolitan Statistical Areas wherein a census tract is deemed to be rural when located within a large metropolitan county of at least 1,225 square miles, but is so isolated from the metropolitan core of that county by distance or physical features as to be more rural than urban in character." *Id.*

[50] 42 CFR § 414.610(c)(5).

[51] 42 CFR § 414.610(c)(6).

[52] *Id.*

[53] 67 FR 9114.

[54] HCPCS code Q3019 has been assigned for claims in which BLS emergency ambulance was provided by an ALS vehicle. Code Q03020 has been assigned for claims in which BLS-non emergency ambulance service was provided by an ALS vehicle. 67 FR 9120.

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Intermediate Sanctions: Applicability in the Healthcare Setting

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I. Introduction

In 1996, Congress enacted the Taxpayer Bill of Rights 2 (TBOR2), which added § 4958 to the Internal Revenue Code (Code) providing for "intermediate sanctions" on certain individuals participating in "excess benefit transactions." The Internal Revenue Service (IRS) has since issued proposed regulations,[ii] that were subsequently replaced by temporary regulations,[iii] which were then superseded by final regulations published by the IRS on January 23, 2002[iv] (the Final Regulations). The publication of the Final Regulations is the culmination of an extended process by which the IRS developed guidelines that will allow it to enforce intermediate sanctions in the form of penalty excise taxes for certain non-fair market value healthcare transactions. This valuable guidance must be considered by tax-exempt healthcare organizations as they enter into various transactions and arrangements.

Despite the release of the Final Regulations, little has been disclosed about the practical application of the guidelines in the context of healthcare system operations. This article will provide a brief overview of TBOR2 and the Final Regulations before presenting a series of hypotheticals for analysis. The intent is to initiate further discussion on the practical impact of these rules upon healthcare systems and to encourage the development of policies that will enhance compliance with the Final Regulations.

II. Summary of TBOR2

Section 4958 imposes excise taxes on "excess benefit transactions" (EBTs) between "applicable tax-exempt organizations" and "disqualified persons." An EBT is any transaction in which an economic benefit is provided by an applicable tax-exempt organization, directly or indirectly, to or for the use by a "disqualified person" that exceeds the value of consideration (including the performance of services) received for providing such benefit. Disqualified persons (as defined below) are subject to a two-tier tax rate as follows: (1) 25% of the excess benefit on each EBT; and (2) 200% of the excess benefit if the EBT is not corrected prior to a formal assessment of the first-tier tax. "Organization managers" who "knowingly" participate in the EBT without reasonable cause to believe it is not an EBT are taxed at 10% of the excess benefit up to a maximum tax of $10,000 per transaction.

The Final Regulations provide that the exempt organization itself is not liable for the penalty excise taxes absent an enforceable indemnity obligation. However, if the excess benefit rises to a level or frequency that calls into question whether the organization as a whole is operated exclusively for charitable purposes, its tax-exempt status could be in jeopardy under a traditional private inurement analysis. In this way, TBOR2 operates as an alternative to the harsh sanction of revoking the tax-exempt status of an entity in all but the most egregious cases.

A. Applicable Tax-Exempt Organization

The intermediate sanctions provisions apply to any organization described in § 501(c)(3) or § 501(c)(4) of the Code and exempt from federal taxation under § 501(a) of the Code at any time during a five-year period ending on the date of an EBT. Note that government entities, such as a state university or a county hospital, whose income is excluded from tax under § 115 of the Code or which is exempt without regard to specific Code sections, is not an applicable tax-exempt organization even if it has obtained an IRS exemption letter describing it as a charitable organization under § 501(c)(3).

B. Disqualified Person

Under § 4958, a "disqualified person" is defined as an individual or entity in a position to exercise "substantial influence" over the affairs of the organization, including their family members (if an individual) and including 35% controlled entities. The Final Regulations provide helpful guidance in making the important determination as to whether an individual or entity is a disqualified person by first defining those positions, which by their nature suggest that an individual exercises "substantial influence" over an entity. Next, the Final Regulations identify those individuals who are not disqualified persons under the rules. Individuals who are defined as having substantial influence include: (1) presidents, CEOs, treasurers and CFOs based upon their actual powers and responsibilities (not merely based on to their titles); (2) persons with a material financial interest in a provider-sponsored organization in which a tax-exempt hospital participates; and (3) a management company, if it has the authority typically associated with a CEO or COO to supervise management. Also, a person with managerial control over a discrete segment of the organization may be a disqualified person when the segment represents a substantial portion of an organization's activities, assets, income or expenses. Additionally, a person whose compensation is based on revenues derived from activities that are within the control of the person may be a disqualified person where the compensation is primarily based on such revenues. Finally, a person whose direct supervisor is not a disqualified person is not likely to have substantial influence over the affairs of the organization and is, therefore, not likely to be a disqualified person. A disqualified person is determined based upon the facts present on the date of the transaction and for a period of five years prior to the date of the transaction.

The Final Regulations set forth several examples in the healthcare industry that are helpful, including an example that provides the head of a hospital's cardiology department is a disqualified person because cardiology is a major source of revenue for the hospital. In contrast, another example provides that a radiologist is not a disqualified person because the radiologist does not receive compensation primarily based on revenues derived from activities controlled by the radiologist

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and does not participate in any management decisions affecting the organization or its activities, assets, income or expenses.

C. Organization Managers

An organization manager is any officer, director or trustee of the applicable exempt organization, or any individual having powers or responsibilities similar to those of officers, directors or trustees, regardless of title. An organizational manager will be subject to the imposition of a tax where he or she knowingly approves of an EBT. Further, a disqualified person may also be an organization manager with respect to a particular transaction.

D. Rebuttable Presumption

Under the intermediate sanctions provisions, an exempt organization may establish a rebuttable presumption with respect to a particular transaction, which transfers to the IRS the burden of establishing that the transaction resulted in an excess benefit. The rebuttable presumption can be established only when the organization adheres to all of the following requirements in connection with a transaction: (1) the transaction or arrangement is approved by an authorized body of the organization (or committee thereof) free of any conflict of interest with respect to the disqualified person and the transaction; (2) the authorized body relies on appropriate data as to the comparability of the compensation or fair market value of the consideration; and (3) the authorized body's determination is adequately and contemporaneously documented. A single individual may be the "authorized body" for purposes of establishing the rebuttable presumption of fair market value under the Final Regulations if state law allows that authority to be delegated to a single individual.

E. Initial Contract Rule

The Final Regulations create an "initial contract rule," not present in the Proposed Regulations, to protect certain fixed payments from intermediate sanctions that are made under a binding written contract to persons who were not disqualified persons immediately prior to entering into the contract. Payments covered under this rule are not EBTs despite the fact that the duties and responsibilities assigned by the contract would render the person a disqualified person. Fixed payments are defined to include an amount of cash or property that is: (1) either specified in the contract or determined using a fixed formula that is set forth in the contract; and (2) to be paid or transferred in exchange for the provision of specified services or property. Payments that include a variable component may qualify as fixed so long as the components are calculated pursuant to a pre-established, objective formula. There is no limit on the number of years a contract may receive protection for fixed payments. However, the initial contract rule does not offer protection for payments made under the contract once it has been materially modified (generally defined as extensions, renewals and a "more than incidental" change in the amount payable) or if the person entitled to receive payments fails to substantially perform his or her obligations under the contract.

III. Hypotheticals in the Healthcare Setting

A. Hypothetical One: Retired Employee

1. Scenario

Hospital is a § 501(c)(3) organization operating a 250-bed community hospital in an affluent midwestern suburb. Hospital's CEO retired on December 31, 2001. The Chairman of the Board feels that in view of the CEO's strong performance and significant contribution to the financial health of the Hospital and increase in charity care and community outreach activities, the CEO deserves a substantial retirement bonus in addition to the deferred compensation he earned in his 10 years as CEO. Based on general "anecdotal knowledge" of these contributions, the Board unanimously approved paying the former CEO a supplemental retirement bonus of $1 million. The CEO had no idea this was happening and was surprised by Hospital's generosity, but quickly accepted the check and deposited it in his investment brokerage account the next day.

2. Model Answer One

CEOs are deemed disqualified persons. With the five-year look-back rule under § 4958, the CEO will remain a disqualified person for at least five years after his retirement. Therefore, if the bonus is not part of a reasonable compensation package consistent with fair market value it would be an excess benefit and would be taxable to the CEO at a rate of up to 225% if not repaid. Whether or not it is fair market value depends on whether the CEO was underpaid during his term of service, and if so, by how much. The payment as described was not part of a pre-approved retirement plan, but rather was added after he retired. There was board approval that may have created a rebuttable presumption, though the anecdotal evidence may not be sufficient evidence of fair market value. The most conservative approach would require the CEO to repay the money immediately, the Hospital to report the transaction on its Form 990, and the CEO to file a Form 4720 without payment of the 25% tax and seek an abatement (since his behavior does not appear willful and he acted promptly when he discovered there may be a problem). Before taking that step, however, it may be worthwhile to retain a consultant to see if the anecdotal evidence is supported in fact. If so, the payment may not be an excess benefit. Failing to investigate the transaction may increase the risk of penalties, and particularly if combined with other EBTs, may show a pattern of EBTs jeopardizing Hospital's exemption. As for the board members as organization managers, if the Bylaws have broad indemnity provisions the board members may be protected from personal responsibility for the 10% tax. If the indemnity applies to the former CEO, however, it too would likely be an excess benefit.

B. Hypothetical Two: The "Taj Mahal" of MOBs

1. Scenario

Hospital administration has conducted a community needs assessment showing a shortage of approximately 25 physicians in various specialties. It pro-

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posed a vigorous recruitment program that included improving facilities and amenities to create a more doctor-friendly healthcare community around the Hospital. One such amenity under consideration is the construction of a new medical office building (MOB) on the Hospital's campus. An independent commercial property management company, ABC Leasing, owns all of the five MOBs located within the 10-mile radius of the Hospital, other than smaller buildings owned and occupied entirely by independent medical practices. ABC rents MOB space to any physician at $15-$18/sq. ft. on a triple net basis, with rents at the newest building being at the high end of that range. The ABC MOBs have an occupancy rate of 80%.

As part of the plan to attract physicians to the community, the administration wants Hospital to build its own MOB on campus. The proposal calls for an ostentatious MOB with marble floors, top-of-the-line furnishings at a documented (from construction contracts and invoices) cost of $20/sq. ft. The plan is presented to the Hospital TBOR2 Review Committee for approval. In his presentation, the CEO notes that they already have verbal commitments from two dozen physicians to move into the space and even one written lease signed by Dr. Haight Tacks, Jr. These commitments are for 10-year leases at $15/sq. ft. in year one with an escalator clause. Dr. Tacks, Jr. is about to complete a residency in California and is interested in moving back home. Rates for other leases have not been set yet, but would be no lower than $15/sq. ft. Coincidentally, Dr. Haight Tacks, Sr. chairs the Hospital TBOR2 Review Committee, ex officio, as the Hospital's Vice President for Medical Affairs. The four other members of the Committee are local business people, including the head of an auto supply firm, a vice president from the local bank, an insurance broker and a retired accountant.

2. Model Answer Two

In analyzing this fact pattern, there are several issues to consider. The first is whether Dr. Tacks, Jr. or any of the other prospective tenants are disqualified persons. We do not know enough about the other tenants, but for planning purposes it is safe to assume that at least some of them will be a disqualified person. Dr. Tacks, Jr. appears to be a disqualified person due to his father being a disqualified person as a result of service on the TBOR Review Committee. Although this is Dr. Tacks, Jr.'s first contract with Hospital, he was already a disqualified person when he signed the lease so he cannot take advantage of the initial contract exception.

Since at least Dr. Tacks, Jr. is a disqualified person, the lease may result in an EBT. The TBOR2 Review Committee needs someone with real estate expertise to tie the pieces together. There are several open questions that could affect fair market value, such as the size of the ABC MOBs, how much space is available in the 20% vacant units, how old and how well maintained the buildings are, and where they are located. The high projected cost of the building also needs to be explained, and the plan to charge less than the cost for the new construction raises the question of whether the rent is fair market value. Incentives to lease a new building are common, but what are the terms of the escalator clause and does it bring the rent up to the building cost or more? How unusual is a 10-year lease in the market as compared to leases at the ABC MOBs, and does the guaranteed rental income justify the net discount? A more basic question is why the Taj Mahal-like construction? There may be structural reasons for the upscale construction or it may have been based on past recruiting efforts and comments from physicians who went elsewhere. It may be based on relevant isolation of the area—the hospital is in an affluent suburb, but is it on the border of an economically depressed area? It also may be based on a desire to make physicians happy even if it results in an MOB that cannot be leased at rates high enough to cover the costs. Those extra amenities would be something of value and, if not paid for, may be an excess benefit.

Even if the $15/sq. ft. rate is less than fair market value, it may be justifiable as part of a reasonable recruitment package. The TBOR2 Review Committee would need to know Dr. Tacks' area of practice and determine whether that specialty is in short supply in the area. There is evidence of a physician shortage, but without the additional information it is not possible to say whether the recruitment of Dr. Tacks, Jr. addresses that shortage.

In order for the TBOR2 Review Committee to create a rebuttable presumption, it needs to be independent as to this transaction. Dr. Tacks, Sr.'s relationship to Dr. Tacks, Jr. creates a conflict of interest. Dr. Tacks should disclose any action he has taken with respect to the MOB project and the leases and should *not* participate in the deliberation or vote on the transactions. These actions and the ultimate fair market value support need to be recorded in the minutes of the meeting.

C. Hypothetical Three: Group Survival

1. Scenario

After abandoning the MOB project, Hospital administration returned to a more traditional, direct physician recruitment plan. First, they updated their community needs documentation by hiring an independent consultant to perform a community needs assessment. That assessment shows a severe shortage of physicians in various specialties in the community, but an oversupply of three OB/Gyns.

The professional corporation owned and operated by Drs. Kash and Floews (PC) employs nine physicians, including two OB/Gyns and seven family practitioners (who also deliver babies). PC is losing money as a group, but it makes a tidy profit on the OB/Gyns. Both OB/Gyns are paid only at the 25th percentile of the Medical Group Management Association (MGMA) salary survey plus $1,000 for each year of experience, despite the fact that each produces at the 50th percentile based on relative value units

(RVUs) and revenues generated for PC. That profit has not been enough to make up the losses on the rest of the practice, and PC has been forced to lay off staff and cut physician pay. Two of the physicians have already threatened to leave town for greener pastures if their pay is not restored by the end of the year. PC has sought help from Hospital, asking Hospital to provide a one-year income guaranty for PC to recruit a third OB/Gyn at the same salary level as the current OB/Gyns (adjusted for seniority). The PC is willing to provide a security interest in the recruit's receivables and to agree to repay any advances at prime +2% if the recruit leaves the community within three years after he or she is hired. The CEO agreed and told you to make it happen.

2. Model Answer Three

The loan terms appear to be reasonable given the interest rate and the security. The recruitment package itself, however, may not be consistent with fair market value since there is an oversupply of OB/Gyns in the area. Hospital would need to demonstrate that circumstances have changed, such as the retirement or relocation of OB/Gyns. Another argument to support the recruitment package may exist if there is a shortage of family practitioners. In the case of a shortage, it may be reasonable to recruit more OB/Gyns to free up family practitioner time because the family practitioners are currently performing some OB services. However, are other OB/Gyns in the community underutilized? Compensation at the 25th percentile seems unlikely to be questioned when productivity is much higher. Additionally, it appears that PC has a history of doing well financially on OB services, which should reduce the likelihood of a significant draw on the guarantee. Another argument in favor of the recruitment package is that if PC does not survive, it could worsen the shortage of family practitioners in the area. The transaction should go before the TBOR2 Review Committee.

IV. Conclusion

The Final Regulations are helpful to tax-exempt healthcare organizations in planning their affairs. Although certain questions remain, such as whether any additional restrictions should apply to revenue sharing arrangements and what additional factors will be considered in determining whether excess benefits jeopardize exemption, the publication of the Final Regulations may make the IRS more willing to issue rulings on intermediate sanctions questions. Even before that guidance is issued, however, it is likely that IRS enforcement activities will increase and we will see more examples of healthcare organizations and their executives and physicians being assessed penalty excise taxes for alleged EBTs. The best protection against those assessments is to make TBOR2 compliance a central and active part of a tax-exempt healthcare organization's compliance program.

Endnotes

1 Portions of the hypotheticals are taken from "Management and Physician Exposure for IRS Intermediate Sanctions," presented in association with Michigan Health & Hospital Association by Ms. Hollenbeck, Gerald M. Griffith and Cynthia F. Reaves of Honigman Miller Schwartz and Cohn, LLP.

2 63 Fed. Reg. 41,486 (Aug. 4, 1998).

3 66 Fed. Reg. 2144 (Jan. 10, 2001).

4 67 Fed. Reg. 3076 (Jan. 23, 2002).

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Current Initiatives in Clinical Research Compliance

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I. Introduction

In recent years, federal regulatory agencies have suspended clinical research studies at several prestigious institutions due to deficiencies in the institutions' human subject protection systems. In some cases, these deficiencies were suspected to have contributed to the deaths of trial participants. As the circumstances and events leading up to these deaths emerged, many expressed concern that the human research participant protection programs had failed to protect their volunteers from unacceptable research risks. These incidents have alerted the public and research community to the inadequacies of the current system of protecting human research subjects and have generated a heightened sense of urgency to implement measures to strengthen those protections.

Medical research programs are under tremendous pressure to complete clinical trials and enhance the delivery of safe products to the marketplace by pharmaceutical companies and others. At the same time, many clinical research trials are being delayed because there are not enough people willing to participate in the trials. The shortage of volunteers can be attributed, in part, to public apprehension stemming from the recent well-publicized negative outcomes for participants in clinical trials. There are mounting concerns about the ability of the current human subject protection systems to keep up with the dynamics and pressures of the medical research environment. Given the current climate, institutions can expect heightened federal oversight and enforcement and more protections for human research subjects. In addition, the federal government is scrutinizing Medicare reimbursement associated with clinical trials and providers face heightened fraud and abuse risks with respect to clinical research payment issues.

This article discusses the following enforcement initiatives in clinical trials compliance: (1) anticipated federal legislation which is expected to add more protections for human subjects, (2) Office of Inspector General (OIG) 2002 Work Plan projects, (3) scrutiny of Medicare reimbursement of clinical trials, (4) proposed FDA regulations aimed at "IRB shopping," and (5) voluntary accreditation programs.

II. Proposed Federal Legislation

Congress may soon mandate more protections and oversight relating to human research subjects. If passed, this would be landmark legislation marking the first significant human subject protection law in over 25 years. In the House, representatives are drafting legislation and are expected to issue a human subject protection bill. Meanwhile, the Senate is conducting extensive investigations to study the issue of human research protection. On April 23, 2002, the Subcommittee on Public Health of the Senate Committee on Health, Education, Labor and Pensions held a hearing on human subject protection.

It is expected that proposed legislation will provide for more oversight of financial conflicts of interest, closer monitoring of ongoing clinical trials, additional resources for institutional review boards (IRBs), improved adverse event reporting systems, and stronger informed consent requirements. The bills may also seek to apply the "Common Rule," a set of regulations for protection of human subjects that govern all federally sponsored research, to all research including privately-funded research.

At the Senate hearing, industry representatives called for legislation that would simplify the clinical research regulations and clarify who has responsibility for enforcement. Currently there are 17 federal agencies that conduct, sponsor or regulate human research programs. A common problem cited by the industry is that these different agencies differ as to how they interpret and apply the Common Rule. Among the recommendations was the establishment of a single, independent federal office to regulate human subject research with the authority to issue a single set of regulations.

Although the proposed legislation has bipartisan support, certain differences, such as whether to make accreditation of human research programs voluntary or mandatory, still need to be ironed out.

III. OIG Work Plan

The Department of Health and Human Services (DHHS) OIG Work Plan for 2002 (Work Plan) takes aim at monitoring clinical research activities using a multi-component approach. The Work Plan would involve the Centers for Medicare and Medicaid Services (CMS), the Office of Research Integrity (ORI), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) in numerous clinical research-related activities including the following:

1. A study of Medicare payments for clinical trials to determine whether clinical trials follow program reimbursement requirements and to assess program safeguards related to clinical trial claim processing.
2. Increased OIG investigation of research misconduct referred by ORI. ORI provides monitoring and oversight to ensure that institutions comply with regulations designed to address allegations of research misconduct including misappropriation of funds, falsification or fabrication of research data or plagiarism of confidential materials or intellectual property.
3. An assessment of CDC controls to preclude conflicts of interest on the part of employees involved in the research awards process.
4. A follow up study on FDA's practices regarding the monitoring of postmarketing studies of prescription drugs.
5. An examination of sponsors' oversight of clinical trials implemented by clinical investigators to ensure that FDA requirements, including human subject protection requirements, are met.

6. A review of NIH oversight of its external grants, including an assessment of NIH's effectiveness in ensuring that grantees properly carry out their research and fiscal responsibilities.
7. An assessment of NIH's procedures for awarding funds to general research centers with a focus on whether NIH has an adequate process for determining whether the centers should be funded using the discrete method (under which the expected costs of research days is included in the grant award and the grant must be reimbursed when center facilities are used for non-research purposes), or on a per diem basis (under which the center is reimbursed for research days actually used).
8. An assessment of investigator efforts to recruit human subjects for NIH clinical trials, including a description of recruitment strategies and oversight of recruitment practices.
9. An evaluation to determine how NIH has applied the mandate of the Bayh-Dole Act to commercialize publicly funded inventions on "reasonable terms." Under the Bayh-Dole Act, federally funded inventions must be brought to practical use within a reasonable time and be made available to the public on "reasonable terms."
10. Ongoing reviews of the adequacy and compliance of college and university disclosure statements to ensure compliance with cost accounting standards, an evaluation of cash management procedures used by selected colleges and universities to account for federally awarded funds, and a review of the allowability of research management service costs charged by a university to federally funded awards.

These activities listed in the Work Plan clearly demonstrate that the clinical research enterprise is a priority area for the OIG.

IV. Reimbursement Compliance Issues

In response to an executive memorandum issued by President Clinton, CMS issued a national coverage decision (NCD) providing that, for costs incurred on or after September 19, 2000, Medicare would cover the routine costs of qualifying clinical trials and reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. The clinical trials NCD raises a host of reimbursement compliance issues and, as noted above, the Work Plan contemplates audits of Medicare payments associated with clinical trials.

A. Key Elements of the NCD

The NCD only applies to "qualifying" clinical trials. A "qualifying" clinical trial must (1) evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage, (2) have a therapeutic intent, (3) enroll beneficiaries with diagnosed disease for participation in trials of therapeutic interventions (although healthy volunteers may be part of a control group in trials of diagnostic interventions), and (4) have "desirable characteristics" that are listed in the NCD. Federally-funded clinical trials and trials conducted under an investigational new drug application are generally presumed to have "desirable characteristics." In the future, CMS will have a process whereby trials can be self-certified as having the requisite "desirable characteristics."

Medicare will cover "routine costs" of a clinical trial which include:

1. Items or services that are typically provided absent a clinical trial (e.g. medically necessary conventional care).
2. Items and services required for the provision of the investigational item or service (*e.g.,* the administration of a non-covered chemotherapeutic agent).
3. Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
4. Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

The following costs are not covered:

1. The investigational item or service itself.
2. Items and services for which there is no Medicare benefit category, which are statutorily excluded, or that fall under a national noncoverage policy.
3. Items and services furnished solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.
4. Items and services customarily provided by the research sponsors free of charge.
5. Items and services provided solely to determine trial eligibility.

B. Fraud and Abuse Risks

All applicable deductible and coinsurance rules apply to clinical trial services with the exception of Part A deductibles for managed care enrollees. The waiver of a co-payment or deductible may be considered an inducement to the Medicare beneficiary and, therefore, a violation of the antikickback prohibitions. However, in Advisory Opinions Nos. 98-6 and No. 00-5, the OIG found that waiver of co-payment and deductibles for clinical trial participants sponsored by HCFA and the National Heart, Lung and Blood Institute to be permissible. OIG noted that the purpose of the waiver was to induce participation in the clinical trial, not to induce the utilization of Medicare covered services. In addition, the research protocol controlled the utilization of services that reduced any risk of overutilization. OIG also recognized that the waiver enhanced patient compliance with the clinical trial. Patients are obviously unlikely to fully participate in a clinical trial if they are required to pay to participate. Further, excluding an individual from access to a drug treatment therapy during its clinical trial phase seems unfair. CMS has, however, offered no guidance as to

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whether co-payments and deductibles may be properly waived for Medicare patients participating in qualifying clinical trials.

Coding and billing Medicare for noncovered research services may give rise to liability under the False Claims Act (FCA). Yet, in some cases, there is no "bright line" test to determine what is a covered research service. For example, it may not be easy to determine what items and services constitute "data collection" for purposes of the trial (and which would not be reimbursable by Medicare), and which medical services are required for monitoring of the effects of the investigational item or service, or the prevention of complications (which would be covered by Medicare).

Billing Medicare for items and services that are reimbursed under the research agreement, by the research sponsor, or a third-party insurer also poses FCA risk. Medicare will not pay for costs funded by a trial sponsor or for items and services typically provided free of charge by the research sponsors. Payment mechanisms by sponsors, however, may not be linked to identifiable costs (for example, under fixed payment per subject or percentage of cost payment arrangements), in which case it may not be easy to determine whether the sponsor intended to pay for services that might be reimbursable by Medicare.

Under the "false certification" theory of FCA liability, a claim may be construed as false simply because it was submitted to the Government by a provider or supplier which has certified compliance with applicable laws and regulations, but has allegedly failed to comply with some underlying requirements associated with the provision of the reimbursable item. Many courts have rejected the theory of false certification, especially where the certification was only implicitly made. In the context of clinical trials, institutions and researchers face risk of FCA liability under the false certification theory due to the myriad of certifications executed in the course of the grants administration process. For example, the DHHS Grant Application (Form PHS 398) contains very broad certification statements signed by the principal investigator and the applicant organization. Also, for dates of service on or after January 1, 2002, the use of the QV modifier on claim forms, which is used to identify and report routine care for Medicare qualifying clinical trial services, constitutes the biller's attestation that the item or service meets the Medicare coverage criteria.

The NCD underscores the need for medical research organizations to institute a billing compliance tracking system for clinical trials. A clinical trials billing compliance tracking system should include the following elements.

1. Confirm whether the clinical trial is "qualified" for purposes of application of the NCD.
2. List all research agreements and identify compensated services. In order to avoid billing Medicare for services that are already reimbursed by the research sponsors, research contracts should detail exactly which medical services are reimbursed by the sponsor.
3. Identify patients who are participating in clinical trials. Patients enrolled in clinical trials who are Medicare beneficiaries and patients enrolled in more than one clinical trial concurrently should be identified.
4. Classify the cost of each type of medical service furnished to the subjects of the trial as billable to a third-party payor, chargeable to a research grant, or absorbed by the institution and/or physicians conducting the trial.
5. Separate charges for items and services related to clinical trials from non-clinical trial items and services on claim forms.
6. The informed consent document should clearly specify any costs that the participants may incur for services included in the protocol, including co-payments and deductibles.

In the face of the OIG's enforcement initiative aimed at Medicare reimbursement associated with clinical trials, medical research institutions and investigators who bill the Medicare program are well-advised to implement an effective billing compliance tracking system immediately. It is critical that the billing compliance plan be communicated and accepted by all components of the institution involved in the conduct of clinical research.

V. IRB Shopping

"IRB shopping" refers to the practice of sponsors and research investigators, dissatisfied with a prior unfavorable IRB review decision, of submitting the same or similar protocol to another IRB. On March 6, 2002, the FDA announced that it was considering new disclosure regulations to address this purported problem. The proposed regulations would require sponsors and investigators to inform IRBs about any prior IRB decisions. Although there is nothing *per se* inappropriate about seeking review of a protocol by a second IRB following an initial negative determination, the FDA and OIG are troubled by the possibility that subsequent IRBs would be unaware of the first IRB's concerns and lack information that would be useful to ensure the safety of human subjects.

Under the proposed FDA regulations, upon submission of a research study, the investigator or sponsor would be required to disclose to that IRB whether the research was previously submitted to an IRB for review. In addition, the investigator or sponsor would be required to disclose the prior IRB's decision on whether to approve or disapprove the protocol.

In an advance notice of proposed rulemaking, the FDA requests information to assist it in deciding whether regulations addressing IRB shopping are necessary, and, if so, how the regulation should operate. The FDA is accepting comments until June 4, 2002. *See Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews*, 67 Fed. Reg. 10115 (March 6, 2002). Specifically, the FDA invited

public comment on the following issues:

1. *How significant is the problem of IRB shopping?* The FDA is requesting objective data regarding the incidence of IRB shopping and specific circumstances in which IRB shopping has occurred (*e.g.*, whether IRB shopping is more prevalent in studies involving vulnerable populations).
2. *Who should make these disclosures?* For example, should sponsors or investigators have a duty to disclose prior negative IRB determinations even if they did not personally submit the protocol to the first IRB?
3. *Who should receive the disclosures?* Under some circumstances, the second IRB may have already approved the protocol before the first IRB rendered an unfavorable determination. Should the disclosure requirements apply if the second IRB has already approved the protocol?
4. *What information should be disclosed?* The FDA seeks comments on whether investigators and sponsors should disclose favorable as well as unfavorable IRB determinations. The FDA also seeks comments as to what constitutes an unfavorable decision (*e.g.,* complete disapproval of a protocol, approval of a protocol with stipulations, or request for significant revisions to the protocol). The proposed regulations may impose additional record keeping requirements on IRBs because IRBs may be required to document and explain their reasons for approving a study, which is not currently a federal requirement. The FDA raised concerns that such a requirement may unduly burden IRBs or lengthen the time need to conduct an IRB review.
5. *How should FDA enforce the requirement?* The FDA seeks comment as to appropriate sanctions for failure of an investigator or sponsor to disclose prior IRB reviews. The FDA noted that it may be difficult to detect noncompliance with a disclosure requirement. In addition, the FDA seeks comments as to whether there are other ways to address IRB shopping other than to require disclosure of prior IRB reviews.

It remains to be seen whether IRB shopping poses a serious threat to the safety of human subjects so as to warrant additional federal requirements.

VI. Voluntary Accreditation Programs

In April 2001, the Institute of Medicine (IOM), an independent body of the National Academy of Sciences created by the Federal Government to advise on scientific matters, called for accreditation of human research participant protection programs in response to events that demonstrated failures in the systems set up to protect the rights and welfare of research volunteers. Both the National Committee for Quality Assurance (NCQA) and the Association for Accreditation of Human Research Protection Programs (AAHRPP) have developed systems to accredit human research programs. The IOM explained that, while compliance with government regulatory requirements is a minimal expectation for a human research protection program, accreditation standards should set forth maximum achievable performance expectations for activities that affect the protection of human research participants.

The NCQA released final standards in August 2001 and is now engaged in a program to accredit IRBs at Veterans Administration medical centers. On February 12, 2002, the AAHRPP released final accreditation standards and procedures.

DHHS announced that it would investigate and audit medical research programs even if they are accredited by NCQA or AAHRPP, and, at this point, would not rely on human subject accreditations to ensure the safety of human subjects. DHHS explained that it would need adequate data to show that such accreditation is working. Notwithstanding DHHS' response, research programs may still want to seek accreditation. Accreditation, as a mark of excellence, may earn public trust and patient confidence, enhance reputations of research centers in the wake of negative publicity surrounding recent clinical trials deaths, and offer a competitive advantage over nonaccredited competitors in seeking sponsor support. Accreditation also helps researchers achieve compliance with government standards and provides a mechanism to identify and correct problems.

VII. Conclusion

As evidenced by these initiatives aimed at clinical research, research institutions face heightened federal oversight and enforcement. An effective institutional compliance program today may be an institution's best strategy to safeguard the integrity of its research projects, the safety of its subjects, and to protect clinical research organizations from liability. An effective compliance program provides a method of internal investigation and review in order to maintain ongoing compliance and reaffirms an institution's commitment to human subject protection.

Hospitals & Health Systems Board Liaison 2002

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The Court is Introduced to Research—A Blind Date Gone Bad: The Kennedy Krieger Institute Lead Abatement Study

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I. Introduction

What happens when an appellate court encounters extraordinary allegations on a sparse record in a procedural appeal, and is nonetheless inspired to fill the void of jurisprudence on human subject research in one fell swoop? In *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807, 366 Md. 29 (2001), the answer was: not much good. The history of the case and the decision are, however, illuminating in many respects and serve as an object lesson to research institutions and their counsel on the increased risks associated with human subject research when subjected to judicial scrutiny.

II. The Study

In 1990, Kennedy Krieger Institute (KKI), whose physicians are faculty members of Johns Hopkins University, was awarded a contract by the Environmental Protection Agency (EPA) to study the effectiveness of various methods of lead abatement in Baltimore by monitoring the blood lead levels of children residing in homes where landlords had made improvements using lead abatement loans. Several methods of abatement had previously been found to result in roughly equivalent dust reduction percentages, but with substantially different costs. The EPA commissioned the study to determine how well the raw dust reductions translated to the actual protection of children from lead absorption with a goal of evaluating the cost effectiveness of the abatement methods. The results had the potential of having a major impact on the availability of low cost housing in many major cities, given the constraints on funding of lead abatement and the fragile economics of lead contaminated housing stock.

III. The Allegations

The suit was brought on behalf of several children who were alleged to have absorbed dangerous levels of lead through participation in the study, and to have had that fact concealed from their parents through a negligent delay in communicating the results of dust tests. The complaint was replete with lurid allegations that KKI was guilty of: 1) deliberately exposing healthy children to lead poisoning to see how little had to be spent to decontaminate housing, 2) taking advantage of low income minority parents by tempting them with food stamps to move into contaminated housing with their children, 3) deliberately concealing from parents that the effectiveness of the lead abatement methods, known to be inadequate, would be determined by taking blood samples from their children to see how much lead poisoning they had suffered, 4) deliberately concealing the discovery of dangerous lead contamination to keep the parents from moving out in order to ensure that the study was completed, and 5) doing all of the above for the enrichment and prestige of KKI. Much of the opinion's rhetorical zeal can be attributed to the court's having to assume the truth of the above allegations for the purposes of the appeal.

IV. The Case on Appeal

The trial court granted KKI's motion for summary judgment, finding that KKI, as no more than a volunteer in the performance of blood tests, did not assume any duties to the plaintiffs more typically associated with the landlord/tenant relationship. The original complaint was in fact predicated largely on traditional landlord/tenant concepts rather than novel theories of liability for breach of duties associated with research, and characterized KKI and the landlords as partners. Not until the appeal, and indeed not until oral argument and the issuance of the opinion was it clear that the case had become the vehicle to examine the duty of principal investigators to subjects, as well as the other issues addressed by the court and beyond the briefs.

On appeal, of course, the court was obliged to assume the truth of the allegations recounted and resolve only the legal issue of whether any duty recognized in law was implicated on the facts as alleged. The sparsity of the record, the procedural posture of the case, the novelty of the issues, and the court's migration from the issues as briefed, all conspired to explain the remarkable opinion. In perhaps no previous summary judgment reversal in Maryland history has the court ever issued so much dicta on novel legal issues that the ultimate facts might not even present, or made so many findings of miscellaneous facts with little or no acknowledgment that there hadn't been a trial yet. It would appear that the court's unconcealed outrage at the allegations inspired a journey through the history of the regulation of research the results of which it applied to the facts alleged, making what it thought were obvious conclusions on issues it felt compelled to address. Most startling was the original holding (clarified somewhat in the ruling on the motion for reconsideration [see below]) that parents lack the legal capacity to consent to the participation of their children in non-therapeutic research with any risk, and must seek judicial approval of same.

That one holding threatened to halt millions of dollars in federally funded research on children because the court did not attempt to define risk and benefit for the purposes of its holding, nor to confine its holding to research outside the risk categories approvable under federal regulations for research involving children (45 C.F.R. 46.404-407). Momentum built for a special session of the Maryland Legislature to clarify parental consent authority, but abated after the court's equally unusual opinion disposing of the motion for reconsideration. The case illustrates what happens when an entire industry develops under the legal radar screen and then suddenly

appears on it. It would perhaps have been too much to expect that the court appreciate the entire regulatory and ethical landscape of human subject research and place the issues presented in perfect context applying conventional jurisprudence to the procedural posture of the case.

The narrow legal issue actually presented was whether the relationship of subject to researcher is a "special" one that will give rise to a duty of reasonable care the breach of which will support a tort action. Viewed from the context of the federal regulatory apparatus for the protection of subjects from risk, the question would almost seem rhetorical. But for the nature of the complaint, which attempted to put KKI in the shoes of a landlord, one could question the strategy of the defendants in even moving for summary judgment, especially given the inflammatory allegations that would necessarily be assumed to be true. It would seem difficult to argue against the existence of a duty on the part of a research institution and it investigators not to dupe parents into letting their children be poisoned to see how little landlords have to spend before they can rent their apartments to the unsuspecting poor.

V. The Opinion

The opinion begins with the ominous admission that the issues presented are novel. The court then wastes no time demonstrating that novelty and jurisprudence do not mix. Only a minimum of ink is spilt, in remanding for trial, on the holding that investigators owe their subjects a duty of reasonable care. Abandoning the salutary appellate reluctance to address peripheral issues that the facts as proven at trial may not even pose, the court devotes the bulk of its lengthy opinion to a wide range of factual and legal issues it perceives to be implicated by the lead abatement study, and indeed its view of the state of human subject research in general. The court even largely dispenses with the standard disclaimer that the facts remain subject to dispute.

Almost without introduction, the court compares the research to the Tuskegee Syphilis Study, the medical experiments in the Nazi concentration camps, and other historical atrocities, and throws in comments about taking advantage of minorities for good measure. The children are compared to canaries in mines. The court then quotes liberally from current published commentary to the effect that reforms are needed to protect subjects from profit motivated research that has compromised subject safety.

The court dismisses the institutional review board (IRB) approval of the study out of hand, casting aspersions on the impartiality of IRBs and the notion of entrusting them with the protection of subjects. Again without disclaimer as to the posture of the case, the court accused the IRB chair of colluding with the principal investigator to evade federal regulations by fabricating the existence of benefits, referring to "the letter from the IRB requesting that the researchers mischaracterize the study." The IRB chair had noted that there was a potential benefit to the blood tests for the control group living in housing constructed without lead paint in possibly detecting lead exposure on playgrounds and elsewhere in the child's environment. The court was not aware—because there had been no trial—that the chairman's suggestion could not have been intended to skirt federal regulations because the existence of a benefit to subjects is completely irrelevant to regulatory approval where the risk to subjects is no more than minimal (the only risk to the control group was that posed by the blood tests themselves, which are uniformly acknowledged as posing no more than minimal risk).

For good measure, the court finds that the consent form was deficient and that the research was so fatally unethical that it was beyond salvage by even a proper IRB process or an adequate consent. The court then enumerates the several respects in which it concluded that the research violated applicable federal regulations, perhaps in the belief that such findings were necessary to avoid any suggestion that compliance with the regulations would insulate KKI from tort liability, but nonetheless without explanation as to the procedural relevance of such findings.

The court finally confronts the issue of parental authority, again apparently on the unstated assumption that it must dispose of what might otherwise constitute a waiver of any duty on the part of KKI. It holds that parents lack the capacity to consent to research in which there are no benefits and any risks, research it perceives as inherently unethical and inappropriate. It is difficult to see why the court saw fit to reach the issue. If proposed research in fact poses more than minimal risk and no direct benefit, it is unlawful for any institution subject to federal regulation to conduct it unless the risk represents a minor increase over minimal risk and there is the likelihood that the research will result in knowledge about the child's disorder. Moreover, any consent that incorrectly characterizes risk as not more than minimal or claims a nonexistent benefit will by definition be uninformed and ineffective. In either event, therefore, the issue of whether a parent could consent to no benefit research involving material risk would not be presented. It would suffice to hold that it is a breach of duty to conduct research that violates federal regulations because it in fact poses more than minimal risk and presents no direct benefit. Instead the court alludes to John Stuart Mills' philosophical examination of consensual slavery and explores the foundation for the requirement that guilty pleas in criminal cases be based on adequate proffers of fact.

VI. The Dissent

The dissent scolds the majority for straying beyond the simple issue of the existence of a duty between an investigator and a subject. Even on that subject it suggests that the issue was one of law alone, not one dependent on any facts for the jury to consider on remand as the majority seemed to hold. The dissent argues pointedly that an entire litany of bald findings of fact were improper in a review of a summary judgment, and that the dicta on legal issues that might never be ripe was imprudent at best, especially given their

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gravity and novelty. The dissent's harshest criticism was reserved for the majority's remarks comparing the research to the Nazi atrocities and the Tuskegee Syphilis Study.

VII. The Motion for Rehearing

As nothing about this case or its jurisprudence could be described as ordinary, it is perhaps not surprising that the unreported *per curiam* denying the motion for rehearing was itself remarkable. In what could only be described as a large Gilda Radner "never mind," the court took great pains to state that its only finding of fact or law was as to the existence of a duty to research subjects, and that all other issues were open for trial, particularly the threshold questions of whether the research involved any risk at all or indeed presented a potential benefit to subjects. It is hard to reconcile that otherwise ordinary concession with the rhetoric of the original opinion. If the research is found to present a benefit to subjects, or not pose any risks, almost the entire original opinion is worse than irrelevant. As for the holding regarding parental authority, the court explained that by "any risk" they meant "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor," but did not clarify whether they intended this standard to correspond to that set forth in 45 CFR 46 with its somewhat different definition of minimal risk. The apparent explanation for the court's retreat is that the briefs on rehearing for the first time educated the court as to the other side of the story, and provided it with analysis of the regulatory context, illustrating the prematurity of jumping to conclusions as to the facts or the issues.

VIII. The Other Side of the Story

KKI has subsequently filed a motion to remove the case to federal court, on the grounds that it is entitled to raise a government contractor defense as to the fundamental design of the study. The petition and conversations with involved parties reveal that the issues are, if anything, more interesting than those posed by the allegations of the complaint. They suggest that the research took place in an entirely different setting than that framed by the plaintiffs.

First, KKI places the study in a factual context to argue that the research itself didn't expose any subject to lead. Subjects were recruited who either already lived in contaminated housing, or had already signed leases on houses that had received lead abatement under the loan programs even before being marketed. For the former, the families were given information about the hazards of lead and told that one of two abatement methods would be undertaken, either of which would be an improvement over the status quo. Families who did not volunteer had no abatement whatever, but were the beneficiaries of the education. For the latter, the landlords had already performed one of two different abatement methods, and as for families renting them, the choice was to participate in the study and receive blood tests, or not. KKI's argument is that participation in the research did not expose any child to increased risk of exposure to lead. Put that way, the study still poses ethical issues, but not exactly those suggested by the allegations in the complaint.

Taking issue with another fundamental predicate of the complaint, it is not conceded that either of the abatement methods was known to be inferior to another in reducing the ultimate risk to children. Each of the methods was in use in many areas of the country based on the lead dust reductions measured in earlier studies. In published studies, all the separate methods had shown a significant reduction in lead dust in vacant homes. KKI explains in its removal petition that the EPA knew only that HEPA filter measurements were comparable, but needed to know whether that comparability translated to reductions in lead absorption by real children and the way they interact with the home environment. It was not known in advance that the more expensive abatement method would result in more protection for children than the others.

KKI's response does, however, raise other issues. Is it appropriate to encourage landlords to perform different lead abatement techniques on their vacant properties for rental to an uninformed public, even if they are not considered research subjects unless they actually participate in the study? Did the project as it related to the vacant homes amount to an experiment, albeit not one subject to federal regulation, on the *non*participating tenants? On the other hand, the lead reduction loans were approved by the state and city and landlords were using the loans to make these improvements absent the study. In addition, all of the methods were in use throughout the country, and just guessing as to their ultimate effectiveness without study is hardly without ethical concern. We may have to await the trial, if any, and subsequent appellate action to see a more thorough examination of the ethical issues actually presented by the KKI lead abatement study.

IX. Conclusion

Despite its flaws, the court's opinion does contain serious discussions of the legal issues that surround the conduct of human subject research. Even with respect to the arguably unnecessary discussion of parental capacity to consent, it is unquestionably valuable to remember that the issue is ultimately a traditional one of state law, not preempted by federal regulations and their categories of permissible research. Similarly, the application of traditional tort and contract duties to the relationships created by human subject research is perhaps inevitable, and the court's discussion is invaluable notwithstanding any procedural shortcomings. Tort liability for research misadventures is a new reality.

Given that participation in research is by definition voluntary, plaintiff's counsel will go directly to the issue of informed consent. In traditional malpractice cases, this count is usually an afterthought which fails on the issue of causation, given that juries are naturally skeptical of plaintiffs who claim that they would not have consented to the removal of their gall bladder had they known all of the rare complications of general anesthesia. In the context of research, by contrast, any defect in the informed consent process may be the

beginning and the end of the case. In the context of research as well, obtaining truly informed consent is more difficult and complex than for routine medical care, involving as it does the fair characterization of speculative benefits and unknown risks together with issues of scientific merit, conflicts of interest, and many others.

Counsel to institutions conducting research on children in particular should examine the quality of the reviews conducted by their IRBs and their compliance with federal requirements, especially those regarding research not presenting the potential of direct or indirect therapeutic benefit. Close attention should be paid to the adequacy of consent documents and the consent process to assure that the research has been candidly explained in terms understandable to its subjects. On top of increased federal scrutiny of research compliance in recent years, the *Grimes* case teaches that research institutions must now assess the adequacy of consent by applying traditional tort perspectives as well.

Hospitals and Health System Annual Meeting Luncheon

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Presenters: **Gerry Griffith, Esquire**, Chair of the AHLA Enron Task Force
Honigman Miller Schwartz & Cohn LLP, Detroit, Michigan
John R. Washlick, Esquire
Cozen O'Conner
Philadelphia, Pennsylvania

Topic: **"Board of Director Responsibilities-Post Enron: Lessons to be Learned"**

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Following the presentation, the speakers will moderate an open-floor discussion soliciting input and feedback from the group regarding how their particular hospital or healthcare system might already be trying to address Enron-related concerns.

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Join Us in San Francisco!

DHHS Publishes for Comment Proposed Revisions to EMTALA

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I. Introduction

On May 9, 2002, the Department of Health and Human Services (DHHS) published for comment, in 67 Federal Register at page 31469, a number of proposed changes and clarifications to the Emergency Medical Treatment and Active Labor Act (EMTALA) regulations found at 42 CFR Part 489. The proposed changes include a new definition, "dedicated emergency department", and clarification of a hospital's responsibilities with regard to maintaining physician on-call lists. The proposed regulations further seek to clarify the murky situations involving EMTALA obligations toward inpatient admissions and the applicability of EMTALA to off campus, provider based departments and provider based entities.

II. New definition—Dedicated Emergency Department

The proposed regulatory changes take on the task of clarifying under what circumstances a hospital is obligated under EMTALA to screen, stabilize or transfer an individual who comes to a hospital, presenting either at its dedicated emergency department or elsewhere on hospital property. DHHS proposes to resolve the question of when, exactly, a patient comes to the emergency department by defining dedicated emergency department as:

> [A] specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical condition and is either located: (1) on the main hospital campus; or (2) off the main hospital campus and is treated by Medicare under § 413.65(b) as a department of the hospital.
> 67 FR 31472.

The proposed definition, according to DHHS, will encompass not only what is generally thought of as a hospital's emergency room, but would also include other departments of the hospital, such as labor and delivery departments, psychiatric units of hospitals that provide emergency care, and any other departments that are held out to the public as an appropriate place to go for urgent medical services. *Id.* DHHS believes that it is irrelevant whether the dedicated emergency department is located on or off the hospital's main campus, as long as the patient is presenting to a hospital for services. DHHS proposes that the new definition of dedicated emergency department would clarify that a hospital must provide at least a medical screening examination to all individuals who present to an area of the hospital meeting the new definition. DHHS is seeking public comment on exactly what constitutes "a significant portion of the time" to determine qualification as a dedicated emergency department.

III. Physician On Call Lists

The subject of physician on call lists has generated much discussion in the provider community, as smaller hospitals have struggled with the extent to which EMTALA requires on-call coverage. DHHS notes, with specific reference to the Centers for Medicare and Medicaid Services (CMS) State Operations Manual, that Medicare does not set requirements on how frequently a hospital's staff of on call physicians are expected to be available to provide on call coverage. 67 FR 31478. It notes "CMS allows hospitals flexibility to comply with EMTALA obligations by maintaining a level of on call coverage that is within their capabilities." *Id.* DHHS notes that there is no predetermined ratio employed by CMS to determine the number of days a hospital must provide medical on call coverage, based on the number of staff physicians. *Id.*

In determining EMTALA compliance, CMS will consider all relevant factors including medical staff size and provisions a hospital has made for situations in which the on call physician is unable to respond or the needed specialty is not available. *Id.* DHHS proposes to add a new paragraph to 42 CFR § 489.24 to specify that each hospital has the discretion to maintain the on call list in a manner to best meet the needs of the patients. It would further specify that physicians, including specialists, are not required to be on call at all times, but that the hospital must have policies and procedure to follow in case on call coverage is not available. 67 FR 31479.

IV. Applicability of EMTALA to Inpatient Admissions

The proposed regulatory clarifications seek to limit the applicability of EMTALA to inpatient situations. If a patient has been admitted as an inpatient, DHHS notes that the hospital's EMTALA obligation continues until the patient is stabilized within the criteria set out in 42 CFR § 489.24(b). 67 FR 31275. A patient who goes in and out of apparent stability with sufficient rapidity or frequency would not be considered stabilized for EMTALA purposes. *Id.* Such a patient would continue to be covered by EMTALA until overall medical stability is achieved.

But for certain limited circumstances as noted above, DHHS opines that EMTALA does not apply to hospital inpatients. *Id.* It bases its analysis on the statutory language itself and the legislative history to reach this conclusion. DHHS reasons that if Congress had intended EMTALA to apply to inpatient treatment, it would not have used a definition of "emergency medical condition" that focuses exclusively on symptoms and that uniquely defines an individual's status at the time of initial presentation to the hospital. *Id.* Further, DHHS notes that the original intent of EMTALA was to address abuses in delivery of emergency medical services; it noted no such references in the legislative history to similar problems faced by hospital inpatients. *Id.*

V. Off Campus Departments and On Campus Entities

In one of the happier proposed changes, DHHS seeks to delete entirely 42 CFR § 489.24(i)

relating to a hospital's EMTALA obligation with respect to patients presenting to off campus departments that do not routinely provide emergency care. 67 FR 31477. Unless an off campus hospital department meets the definition of designated emergency department as noted *supra,* it would have no EMTALA obligation with respect to patients presenting to such departments. *Id.* Under the circumstances of a patient presenting to a hospital department that did not meet the definition, it would be appropriate for the department to call the EMS, if it is incapable of treating the patient. *Id*. However, DHHS expects that hospitals will have appropriate protocols in place to address such situations. *Id*. DHHS proposes adding a new paragraph to 42 CFR § 482.12, requiring that the governing body of the hospital assure that the hospital medical staff has written policies and procedures in effect with respect to off campus non emergency departments for appraisal of emergencies and referral when appropriate. *Id.*

Finally, the proposed changes clarify that provider based entities that are not under the certification and main provider number of the hospital do not incur EMTALA obligations. EMTALA applies only to those (hospital) *departments* (emphasis present in original) on the hospital's main campus that are provider based, and would not apply to provider based *entities* (emphasis present in original) (such as RHCs) that are on the hospital campus. *Id*.

VI. Conclusion

The proposed regulations provide much needed clarification of a hospital's EMTALA obligations in several situations that had been less than clear. Except for certain limited circumstances, DHHS makes it clear that EMTALA would not apply to inpatients. By providing a new definition of designated emergency department, DHHS has gone a long way toward resolving providers' questions as to when EMTALA obligations attach. The proposed changes to the EMTALA regulations appear to narrow, not widen, the scope of the Act. Comments on the proposed changes are due no later than 5:00 p.m. on July 8, 2002.

Upcoming Practice Group-sponsored Teleconferences

The Practice Groups are making plans for the new fiscal year (beginning July 1). Here are some teleconferences that you won't want to miss so mark your calendars now and look for upcoming registration information.

Lessons from Enron for the Healthcare Sector
Thursday August 1 and Thursday August 8, 2002
1:00-3:00 pm (Eastern) both days
Sponsored by the Tax and Finance; Hospitals and Health Systems; and Healthcare Liability and Litigation Practice Groups

The Application of Nonprofit Corporate Law to Healthcare Organizations
Thursday, September 12, 2002
1:00-2:30 pm (Eastern)
Based on the recently issued monograph of the same title by Michael Peregrine and James Schwartz

Latest Litigation in Survey/Cert
Wednesday, September 25, 2002
1:00-2:30 pm (Eastern)
Sponsored by the Long Term Care Practice Group

Tax Exemption Issues in Compliance
Fall 2002
Sponsored by the Tax and Finance Practice Group

Conflicts of Interest in Clinical Trials
Fall 2002
Sponsored the Teaching Hospitals and Academic Medical Centers Practice Group

Reimbursement Issues
Fall 2002
Co-sponsored by the Long Term Care and Regulation, Accreditation, and Payment Practice Groups

Problems with Non-Geriatric Residents in Nursing Homes
Fall 2002
Sponsored by the Long Term Care Practice Group

For more information on these teleconferences, go to: http://www.healthlawyers.org/teleconferences.cfm

The Office for Civil Rights Releases Proposed Modifications to the HIPAA Privacy Standards

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I. Introduction

On March 21, 2002, the Office for Civil Rights (OCR) released a proposed rule (Proposed Rule) containing proposed revisions to the federal Standards for Privacy of Individually Identifiable Health Information codified at 45 C.F.R. Parts 160 and 164 (Privacy Standards).

The Privacy Standards became effective April 14, 2001. The compliance date for covered healthcare providers, healthcare clearinghouses and most health plans is April 14, 2003. For small health plans with annual gross revenues less than five million dollars ($5,000,000), the compliance date is April 14, 2004. The Proposed Rule does not change the compliance dates for the Privacy Standards. The Proposed Rule only provided a thirty (30) day comment period that ended on April 26, 2002.

The Proposed Rule purports to clarify and simplify key provisions of the Privacy Standards while still maintaining protection for individually identifiable health information.

II. Consent

Probably the most significant revision proposed by OCR is removal of the requirement that covered direct treatment healthcare providers obtain a consent before the provider can use or disclose protected health information (PHI) to carry out treatment, payment, or healthcare operations. Compliance with the consent requirement of the Privacy Standards would create several complications under certain circumstances. For example, if a physician calls a pharmacy with a patient's prescription, and the patient had not previously executed a consent with the pharmacy, the pharmacy would be prohibited from using or disclosing the PHI about the patient to fill the prescription until the patient arrived in person and signed a consent.

All covered entities will be permitted to obtain a consent if they so choose. Moreover, the removal of the consent requirement only applies to uses and disclosures of PHI for treatment, payment, and healthcare operations; it does not change the obligation of a covered entity to obtain an authorization for uses and disclosures of PHI not otherwise permitted by the Privacy Standards.

III. Use and Disclosure of PHI.

According to the Privacy Standards, a covered entity, after obtaining a consent, is permitted to use or disclose PHI to carry out treatment and the covered entity's own payment and healthcare operations. However, a covered entity is generally prohibited, absent obtaining an authorization, from disclosing PHI to another entity for the receiving entity to carry out its own payment or healthcare operations.

OCR proposes to clarify and simplify existing uses and disclosures of PHI covered entities are permitted to conduct, without the necessity of obtaining an authorization, by revising 45 C.F.R. § 164.506 to:

1. Permit covered entities to use or disclose PHI for their own treatment, payment, or healthcare operations without prior consent or authorization.
2. Clarify that covered entities may share PHI for the treatment activities of another healthcare provider.
3. Permit covered entities to disclose PHI to another covered entity or non-covered healthcare provider for the purpose of such receiving entity to carry out its own payment activities.
4. Permit covered entities to disclose PHI about an individual to another covered entity in order for the receiving covered entity to carry out certain healthcare operations listed in paragraphs 1 & 2 of the definition of "healthcare operations." This revision would further require that both covered entities have, or have had a relationship with the individual who is the subject of the information being requested. Under this provision, covered entities would only be permitted to disclose PHI to another covered entity.
5. Clarify that covered entities participating in an organized healthcare arrangement (OHCA) may share PHI for the healthcare operations of the OHCA. The Privacy Standards permit legally separate covered entities that are clinically or operationally integrated to be considered an OHCA if the participating covered entities must share PHI for the joint management and operations of the arrangement.

IV. Notice of Privacy Practices

OCR proposes to require covered direct treatment healthcare providers to make a good faith effort to obtain an individual's written acknowledgment of receipt of the healthcare provider's notice of privacy practices. Indirect treatment healthcare providers, health plans and healthcare clearinghouses are not required to obtain this acknowledgment.

While the Proposed Rule requires that the acknowledgment be in writing, however, the format of the acknowledgment is not set forth in the Proposed Rule. OCR states that each covered healthcare provider may choose the form and other details of the acknowledgment that are best suited to the provider's practices so long as they do not pose an impediment to the delivery of timely and quality healthcare . In the event of an emergency situation, OCR proposes to permit healthcare providers to delay provision of a notice of privacy practices until reasonably practicable after the emergency treatment situation. Healthcare providers would further be exempt from having to make a good faith effort to obtain the acknowledgment in an emergency treatment situation.

While covered direct treatment healthcare providers would no longer be required to obtain a patient's consent prior to carrying out treatment, payment or healthcare operations, any uses or disclosures of PHI for such purposes would still need to be consistent with the entity's notice of privacy practices.

V. Minimum Necessary and Oral Communications—Incidental Use or Disclosure

The Privacy Standards require that covered entities take reasonable steps to limit uses or disclosures of, and requests for, PHI to the minimum amount necessary to accomplish the intended purpose of the use, disclosure or request. Covered entities must evaluate their practices and implement protections, as needed, to limit unnecessary or inappropriate access to, and disclosures of, PHI. Covered entities are required to develop and implement policies and procedures appropriate to the entity's business practices and workforce that reasonably minimize the amount of PHI used, disclosed, and requested. In addition, such policies and procedures must identify the persons or classes of persons within the covered entity who need access to PHI to carry out their job duties, the categories or types of PHI needed, and conditions appropriate for such access.

OCR proposes to modify the Privacy Standards to explicitly permit certain incidental uses and disclosures that occur as a result of an otherwise permitted use or disclosure of PHI under the Privacy Standards. An incidental use or disclosure must:

1. Be a secondary use or disclosure that cannot reasonably be prevented,
2. Limited in nature, and
3. Occur as a by-product of an otherwise permitted use or disclosure under the Privacy Standards.

OCR proposes to permit incidental uses or disclosures of PHI only to the extent that the covered entity has applied reasonable safeguards, and has implemented the minimum necessary standard, where applicable. Any incidental use or disclosure that occurs as a result of a covered entity's failure to apply reasonable safeguards or the minimum necessary standard would violate the Privacy Standards. For example, a covered entity that asks for a patient's health history on the waiting room sign-in sheet is not abiding by the minimum necessary requirements and, therefore, any incidental disclosure of such PHI that results from this practice would be an unlawful disclosure under the Privacy Standards.

Furthermore, OCR proposes to exempt from the "minimum necessary" standard, any use or disclosure of PHI for which the covered entity has received an appropriate authorization.

VI. Business Associate Agreement

OCR has received numerous comments contending that large covered entities would not have enough time to review and revise or renegotiate all of their existing vendor and service contracts in order to bring such contracts into compliance with the business associate requirements contained in the Privacy Standards. OCR, therefore, proposes to permit covered entities to continue to operate under certain existing contracts with business associates beyond the April 14, 2003 compliance date. The extension would apply to agreements that are already in effect on April 14, 2003. The agreement, however, must be brought into compliance with the business associate requirements the sooner of the next renewal date of the agreement or April 14, 2004. OCR further provides model business associate language for business associate contracts; however, the provided model language does not include other key, although not required, contract language such as an indemnification clause.

VII. Marketing

OCR proposes to eliminate the special provisions for marketing health-related products and services. Instead, any communication defined as "marketing" would require an authorization by the individual. Covered entities would no longer be able to make any type of marketing communications without an authorization unless the communication is face to face or it involves a promotional gift of nominal value.

The requirement that a covered entity obtain an authorization for marketing does not include communications made to an individual:

1. To describe the entities participating in a healthcare provider network or health plan network, or to describe if, and the extent to which, a product or service (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, healthcare providers, or settings of care to that individual.

Furthermore, if the covered entity is going to receive remuneration for the advertising, the authorization must indicate so.

VIII. Disclosures of Protected Health Information Regarding Parents and Minors

OCR proposes to revise the provisions related to disclosure of PHI to the parents of a minor child to clarify that state and other applicable law governs when such state law explicitly addresses disclosure of a minor's PHI to the minor's parent and on such occasions when such state law provides discretion to a healthcare provider to disclose the minor's PHI to the minor's parent.

IX. Research

Under the Privacy Standards, covered entities are permitted to use or disclose PHI for research purposes with an authorization from the individual research participant or without an authorization if the covered entity's institutional review board or privacy board waives the entity's obligation to obtain an authorization, provided certain criteria are followed.

A. Waiver Criteria

OCR proposes to revise the waiver of authorization criteria with regard to conducting research. The revisions will make the waiver criteria more reflective of the requirements for waiving informed consent set forth in the "Common Rule." OCR proposed to

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retain two of the waiver criteria contained in the Privacy Standards due to their similarity to two of the Common Rule criteria. In addition, the revised waiver criteria would compound three criteria OCR believes are important to determining whether the research proposes a minimal risk to the participant. The authorization waiver criteria would apply whether or not the research project is subject to the Common Rule. The proposed waiver criteria are as follows:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   a. An adequate plan to protect the identifiers from improper use and disclosure;
   b. 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
   c. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by 45 C.F.R. § 164.512(i);
2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to and use of the PHI.

OCR further proposes to revise the research standard by eliminating the provision requiring a specific authorization for a covered entity to use and disclose PHI for research which includes treatment of the research participant. Covered healthcare providers will still be able to condition the provision of research related treatment on the research participant first providing an authorization for the use and disclosure of the research participant's PHI for the particular research study.

In addition to eliminating the special authorization requirements for research studies involving treatment, OCR proposes to clarify that the Privacy Standards will allow an authorization for the use or disclosure of PHI for research to be combined with any other legal permission related to the research study including another authorization or an informed consent. With regard to the timing requirement for termination of an authorization, OCR proposes to allow the statement "end of the research study" or similar language to be sufficient to satisfy the requirement for an expiration date or event.

B. Research Transition

The proposed research amendments would eliminate the distinction between research that includes treatment and research that does not include treatment. In addition, there will be no distinction between requirements for research conducted with a patient's informed consent versus research conducted with an IRB-approved authorization waiver.

A covered entity would be permitted to use or disclose PHI for a specific research study that is created or received either before or after the compliance date, if the covered entity has obtained, prior to the compliance date: an authorization or other express legal permission from an individual, an informed consent to participate in the research study, or an IRB has waived informed consent for the research study in accordance with the Common Rule or the FDA's human subject protection regulations.

X. Authorization

The Privacy Standards provide for three types of authorizations that may be used for the use and disclosure of PHI not otherwise permitted under the Privacy Standards. OCR, intending to simplify the authorization provisions, is proposing to only require one type of authorization for all uses and disclosures of PHI not otherwise permitted under the Privacy Standards.

All authorizations would contain the following core elements:

1. A description of the information to be used or disclosed,
2. The identification of the persons or class of persons authorized to make the use or disclosure of the PHI,
3. The identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure,
4. A description of each purpose of the use or disclosure,
5. An expiration date or event,
6. The individual's signature and date, and
7. If signed by a personal representative, a description of his or her authority to act for the individual.

In addition to modifying the core authorization requirements, OCR is proposing to require authorizations to contain the following notifications:

1. A statement that the individual may revoke the authorization in writing and either a) a statement regarding the right to revoke the authorization, and instructions on how to exercise such right, or b) to the extent that this information is included in the covered entity's notice of privacy practices, a reference to the notice;
2. A statement that treatment payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Standards, or, if conditioning is permitted by the Privacy Standards, a statement about the consequences of refusing to sign the authorization; and
3. A statement about the potential for PHI to be subject to re-disclosure by the recipient of such PHI.

XI. De-Identification

While OCR is not proposing to revise the enumerated identifiers, it does propose to clarify its intent by explicitly excluding from the list of enumerated identifiers, the re-identification

code or other means of record identification.

XII. Other Technical Corrections

1. OCR proposes to add language to the definition of "healthcare operations" to clarify its intent to permit the transfer of records to a covered entity upon a sale, transfer, merger, or consolidation. This proposed change would prevent the Privacy Standards from interfering with necessary treatment or payment activities upon the sale of a covered entity or its assets.
2. OCR proposes to clarify that group health plans (or health insurance issuers or HMOs, as appropriate) are permitted to disclose enrollment or disenrollment information to a plan sponsor without meeting the plan document amendment and other related covered entity requirements.
3. OCR proposes to expand the exceptions to an individual's right to an accounting of a covered entity's disclosures of the individual's PHI to include disclosures made pursuant to an authorization. Covered entities would no longer be required to account for any disclosures authorized by the individual.
4. OCR proposes to delete the term "primary" from the definition of "hybrid entity." This would permit any covered entity to be a hybrid entity if it is a single legal entity that performs both covered and non-covered functions, regardless of whether the non-covered functions represent that entity's primary function, a substantial function, or even a small portion of the entity's activities. Covered entities that could qualify as hybrid entities would be permitted to choose whether or not they want to be considered hybrid entities.
5. OCR proposes to expressly exclude employment records held by a covered entity in its role as an employer from the definition of PHI.

XIII. Conclusion

The proposed revisions, if finalized, would likely ease the implementation of the Privacy Standards for covered entities and clarify other provisions whose interpretation would create compliance difficulties. The Proposed Rule leaves intact the individual rights provisions of the Privacy Standards with the exception of the addition of authorizations to the accounting exceptions.

American Health Lawyers Association depends upon the participation of its members. We appreciate the contributions of the following individuals to this edition of the Hospitals and Health Systems SISLC Newsletter:

About the Editor

Cynthia F. Reaves, Esq. (Editor and Project Task Force Chair) is a partner with the healthcare practice of Honigman Miller Schwartz and Cohn LLP in Detroit, Michigan. Ms. Reaves provides legal counsel to managed care organizations, hospitals and health systems, integrated delivery systems, university-affiliated healthcare entities, pharmaceutical companies, and other healthcare service providers. Ms. Reaves' practice focuses on corporate and transactional, tax-exempt, health regulatory, HIPAA privacy, e-health commerce, and Hart-Scott-Rodino application and prosecution issues for health industry clients. Ms. Reaves has represented clients before a variety of state and federal agencies, including the Internal Revenue Service. She serves on the Editorial Board of *The Healthcare Compliance Portfolio* published by Commerce Clearing House and has spoken and published extensively on healthcare topics. Ms. Reaves is the co-author of the book *Recruiting, Compensating and Retaining Physicians* (2000, Atlantic Information Services, Inc.).

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Ralph L. Glover, Esq. is an associate attorney with the law firm of Michael Best & Friedrich, LLC in Chicago, Illinois. He counsels health care providers in a wide array of corporate and regulatory issues, including licensure, certification, reimbursement, medical staff, human research, fraud and abuse, managed care, EMTALA and HIPAA privacy and security compliance.

Marc Goldstone, Esq. serves as General Counsel for the Monmouth Ocean Hospital Service Corporation (MONOC). MONOC is an IRC §501(e) hospital shared services consortium that operates an integrated medical transportation system in Monmouth, Ocean and Atlantic counties, New Jersey. MONOC's ambulances respond to more than 75,000 requests for service per year, and provide more than 60,000 incidents of patient care and/or transportation each year. Mr. Goldstone is a member of the

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American Health Lawyers Association, the New Jersey Bar Association's Health and Hospital Law Section, and the Health Law Section of the American Bar Association. Mr. Goldstone regularly participates in AHLA activities, and was most recently published in AHLA's Physician Organizations' SISLC's newsletter. Mr. Goldstone maintains an active consulting practice, serving health systems, hospitals and ambulance providers throughout the country. Mr. Goldstone in admitted to the Bars of New Jersey and Pennsylvania, and has been certified by the State of New Jersey as a Mobile Intensive Care Paramedic since 1988.

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Alan P. Richman is President and CEO of InnoVative Capital, headquartered in New York City. Mr. Richman's expertise extends to all areas of credit enhancement including, but not exclusive to: FHA mortgage insurance, Fannie Mae bond enhancement, bank letters of credit, GIC's and municipal bond insurance. InnoVative Capital provides financial advisory services to hospitals and the health care industry and is an FHA-licensed mortgage banking company and a HUD-approved MAP lender specializing in hospital and health care finance and HUD Section 242 Hospital Mortgage Insurance.

Joseph V. Truhe, Jr. became corporate counsel to Children's National Medical Center in 1998, and served on its Institutional Review Boards, after 20 years in the private practice of Health Law. He graduated from Yale University in 1974 and the University of Virginia School of Law in 1977, and is a frequent author and speaker on research compliance and other health care topics.