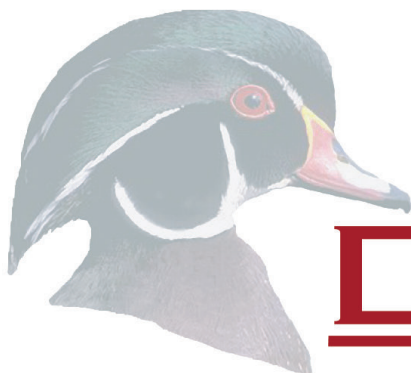


Releasing Protected Health Information

The History and the Regulations

Prepared by Kenneth E. Rhea, MD, FASHRM

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Introducing

Kenneth E. Rhea, MD, FASHM

Dr. Rhea is a medical liability and risk consultant to medical practices and other health related organizations. He was in medical and surgical practice for over 30 years and for the past 17 years has been a consultant in medical risk and liability management. He is the owner and Managing Partner of Medical Education and Risk Consulting, called MER Consulting. Dr. Rhea has been dealing with risk and federal regulatory compliance areas such as the HIPAA privacy and security regulations beginning with the Privacy Rule in 2000.

Dr. Rhea will write monthly white papers on various sections of the HIPAA regulations in regard to those most encountered in office practice. The information will be summarized from actual federal law with both references and multiple choice questions for your teaching use.

HIPAA training is required by the regulations and must be ongoing. This monthly information can be used as part of efforts to meet those requirements. These HIPAA articles can be used and documented as part of your staff and administrative training program.

While these educational materials will not by any means cover everything you need to do for HIPAA privacy and security compliance they provide more documented evidence of training and intent to comply.

If you have any questions on the information Dr. Rhea can be contacted directly.
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The following news report from Fox News and the AP appeared August 1, 2014:

*"Plans are underway to bring back the two American aid workers sick with Ebola from Africa. A small private jet based in Atlanta has been dispatched to Liberia where the two Americans work for missionary groups. At least one of the Americans is expected to be treated in the U.S. at Atlanta's Emory University Hospital, which has a special isolation unit. **The hospital declined to identify the patient, citing privacy laws.** The private jet can only accommodate one patient at a time. In a press conference Friday afternoon, Emory's Dr. Bruce Ribner, said the facility had been informed that two patients were coming to the facility; one in a few days, the next a few days after that.." [Edited with highlight] ¹*

It was assumed that the "privacy laws" referenced were the HIPAA regulations related to the privacy and security of individually identifiable health information that was protected health information (PHI). Clearly the decision to refuse identification was made, but was such a decision required?

THE HISTORY

The enforcement of HIPAA regulations has become very aggressive by the OCR over the past 3 years and is expected to continue with a new phase of medical practice audits having started in October 2014.

Recently a physicians group was the subject of an Office for Civil Rights (OCR) investigation for the mishandling of paper records involving some 5,000 patients related to a retiring physician. There were findings of HIPAA privacy and security regulations violations. After the investigation the group entered into what is known as a "Resolution Agreement" and an associated "Corrective Action Plan". The Plan among other things required policy reviews over the next year, staff training and a monetary penalty of \$800,000.

Another medical organization was recently investigated when one of the physicians in the group lost a laptop computer containing unprotected patient information. This investigation also found HIPAA regulation violations. The result was also a Resolution Agreement and a Corrective Action Plan lasting a more customary 3 years with an agreed penalty of \$1,500,000.

These cases are examples of medical practices failing to have in place necessary HIPAA compliance programs.

We have now also seen the first diagnosis of Ebola infection in the US at Texas Health Presbyterian Hospital, Dallas, Texas on September 26, 2014. Thomas Eric Duncan, a Liberian man who traveled from Monrovia to Dallas was evaluated at the hospital on September 24, 2014, was released, later readmitted with eventual death October 8, 2014. On October 12, 2014 it was announced that a hospital employee working with Mr. Duncan had contracted the first transmitted case of Ebola infection.² Once again the hospital elected not to identify the new patient stating wishes of the family.³ The patients survived the infection, but the actions and the stance of the hospital and government were widely discussed in the media with extensive commentary and speculation on medical actions and the eventual effects of the Ebola virus in the US. Most authorities feel that this threat while not receiving as much media attention in the remainder of 2014 has not ended, e.g., limited control in several African nations. The White House "Ebola Czar" says "... Americans should expect more domestic cases..."⁴

While the eventual course of this virus in the US is unknown there are several things that can be stated with certainty. One is that the HIPAA regulations on the privacy and security of protected health information are in place, regulations have

"HIPAA regulations must be understood by every physician and medical practice in order to make appropriate decisions to protect health information"

not changed due to the Ebola concerns, and regulations apply to situations of patients having or who are suspected of having Ebola infection as well as other medical conditions. Another is that requests for patient status, types of treatment, and other information involving PHI will frequently be requested by third parties such as relatives and media. The allowed disclosure of protected health information (PHI) under the HIPAA regulations must be understood by every physician and medical practice in order to make appropriate decisions to protect health information.

THE REGULATIONS

The action of allowing disclosure of PHI has been addressed since the Privacy Rule, the first of HIPAA privacy and security regulations with required compliance by April 14, 2003. Modifications and additions to regulations have occurred as recently as the Omnibus Final Rule in 2013. Patients have always had a right under these regulations to request their protected health information (PHI) as stated in 45 CFR §164.524 (1) a right of patient access to PHI maintained in a designated record set exists as long as the information is retained in the record set.⁵ However there are some exceptions such as whether or not the PHI involves "(i) Psychotherapy notes; (ii) Information compiled in reasonable anticipation of, or for use in, a civil,

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may be denied
to patients in a
number of situations"

criminal, or administrative action or proceeding;
and (iii) Protected health information maintained
by a covered entity" that is subject to the Clinical
Laboratory Improvement Amendments 1988 with
access prohibited or is exempt from the these
amendments.⁶ Also access to PHI may be denied to
patients in a number of situations some of which
allow review of the decision to deny access and
some which do not.

In certain situations use or disclosure of protected
health information requires an opportunity for the
patient to agree or object, e.g., facility directories,
involvement in a persons care, and for notification
purposes.⁷

The Privacy Rule "... recognizes that covered
entities must balance protecting the privacy of
health information with sharing health information
with those responsible for ensuring public
health and safety, and permits covered entities
to disclose the minimum necessary protected
health information to public health authorities or
other designated persons or entities without an
authorization for public health purposes specified
by the Rule." ⁸ The areas of access prominently
associated with high profile medical treatment
such as possible Ebola virus cases may involve the
release of protected health information to third
parties either related or unrelated to the patient

"the physician does not need permission from the patient to use or disclose the PHI in certain situations"

and in situations where such release has not been requested or authorized by the patient. In respect to patient permission to release information HIPAA regulations specifically allow for the "uses and disclosures for which an authorization or opportunity to agree or object is not required" .⁹ Stated in another way the physician does not need permission from the patient to use or disclose the PHI in certain situations. These include:

- victims of abuse, neglect, or domestic violence
- health oversight activities
- judicial and administrative proceedings
- release related to decedents
- cadaveric donation purposes
- research purposes
- specialized government functions
- workers' compensation.¹⁰

Of particular interest are four additional categories which may be particularly relevant to medical care of patients with threatening diseases such as Ebola virus infection. These are:

- law enforcement purposes,
- uses and disclosures required by law and to the limited extent required by law
- "use or disclosure to avert a serious threat to health or safety"
- "uses and disclosures for public health activities" .¹¹

"Limited disclosures to law enforcement authorities may also be done"

In relation to the first two involving law enforcement and disclosures required by law the information may be disclosed, but within limits, i.e., the "... use and disclosure complies with and is limited to the relevant requirements of such law" .¹² This may include judicial and administrative proceedings mentioned above and may require "satisfactory assurance". This would include assurance such as written statements and necessary documentation of necessary actions for a "protective order" , i.e., "an order of a court or administrative tribunal" or a "stipulation" by the requesting party limiting the use of the PHI and return or destruction of the PHI after the intended use.¹³ Release is also possible by the covered entity (CE) if "reasonable efforts" have been made to obtain a qualified protective order.¹⁴ Disclosure for other law enforcement purposes might include those "pursuant to process" such as a court order, a court-ordered warrant, a subpoena, or summons "issued by a judicial officer" .¹⁵ Also included are administrative requests, administrative subpoenas, administrative summons, a civil demand, or an "authorized investigative demand." ¹⁶ Limited disclosures to law enforcement authorities may also be done for requests involving identification and location of a person, for victims of a crime, decedents, crimes on the premises of the covered entity (CE), and reporting crime in emergencies. In any case the PHI requests cannot be total and must be "relevant and material" to

"the most prominent regulatory areas will be those of public health activities and averting serious threats to health and safety"

the law enforcement inquiry and be "...specific and limited in scope to the extent reasonably practicable..." , e.g., in situations of identification and location purposes the covered entity (CE) may disclose to the requesting law enforcement official only certain information including name and address, date and place of birth, SS number, blood type and Rh factor, type of injury if any, date and time of treatment or death, and a description of "...distinguishing characteristics..."¹⁷

While law enforcement has been and in the future might well be involved in activities related to infectious disease problems such as Ebola infection with a need for understanding of HIPAA regulations by healthcare providers, the most prominent regulatory areas will be those of public health activities and averting serious threats to health and safety.

Of prominent note is the allowance of use and disclosure of PHI in situations of "...public health surveillance, public health investigations, and public health interventions..." when such activities are for the "...purpose of preventing or controlling disease, injury, or disability, including, but **not limited to**, the reporting of disease..." to "A public health authority that is authorized by law to collect or receive such information..."¹⁸ These situations as many others require appropriate

"PHI may be released to a "...public health authority or other appropriate government authority authorized by law..." to receive information about child abuse or neglect"

identification of the requesting person for authorities with complete record documentation by the healthcare provider.

Equally in force, but not as closely related to problems of infectious disease are uses and disclosures of PHI for public health activities "... for the purpose of activities related to the quality, safety or effectiveness..." of "...an FDA regulated product or activity..." . This applies if the requesting person is "subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility..." .¹⁹ Also, PHI may be released to a "...public health authority or other appropriate government authority authorized by law..." to receive information about child abuse or neglect.²⁰ A school may also receive PHI under defined criteria.²¹

With considerations of "...applicable law and standards of ethical conduct..." PHI may be released under the second major category of averting a "...serious threat to health or safety..." such as might be the case with Ebola infection.²² These kinds of PHI releases by a healthcare provider can be done if the covered entity believes "...in good faith..." that such a release will in his/her best judgment "...lessen a serious and imminent threat to the health or safety of a person or the

public;" and that the person to whom the PHI is provided is someone who is "reasonable able to prevent or lessen the threat..." .²³

"In all of the situations relating to the aversion of a threat to health and safety there is a "presumption of good faith belief""

In other situations relating to violent crime such releases can be made by a covered entity allowing law enforcement to "identify or apprehend" an individual unless the information obtained by the covered entity has been obtained in the course of treatment, counseling, therapy or the request for such. ²⁴ In these situations there is a restriction of the amount of PHI released to only the "statement" by the person about a violent crime.²⁵

In all of the situations relating to the aversion of a threat to health and safety there is a "presumption of good faith belief" meaning that the covered entity has relied on his/her actual knowledge or the "...credible representation by a person with apparent knowledge or authority." ²⁶

The HIPAA regulations in many instances provide for healthcare provider medical decisions which will be in the best interest of privacy and security of PHI, but which will also serve the public health and safety. In the earlier situation the hospital was not specifically constrained by the regulations to refuse patient identification. Instead, as shown in the discussion above, the regulations allowed a choice. In the case of the 1st Ebola diagnosis in the US and the later 1st proven transmission of Ebola at

"In some cases situations of individually identifiable health information are also addressed by state law"

the same hospital the decision not to identify was allowable, though PHI could have been released if the healthcare provider felt that one of the above criteria applied.

In all situations the general prime interest is the best protection of health information consistent with requirements. In some cases situations of individually identifiable health information are also addressed by state law. In these situations if a provision of federal law is "...contrary to a provision of state law..." federal law preempts state law unless the Secretary of HHS might for several reasons determine otherwise or the state law "...is more stringent..."²⁷ The determination of whether some provision is "contrary" is based on whether a "...covered entity or business associate would find it impossible to comply with both the state and federal requirements" or "...The provision of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives..." of the federal law.²⁸

THE SUMMARY

The short summary is that in these situations, as well as many other medical situations, choices are available, but knowledge of what HIPAA regulations and other laws allow is necessary. Every healthcare professional should therefore be aware of these allowed uses and disclosures not

"final informed decisions must then be made within the regulatory allowances based on good medical judgment. "

only for the purpose of covered entity compliance with regulations and avoidance of potential civil or criminal penalties, but for provision of appropriate medical care and assistance with public health. The final informed decisions must then be made within the regulatory allowances based on good medical judgment.

Questions and Answers after the Endnotes section.

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REVIEW QUESTIONS

Question 1 The following news report from Fox News and the AP appeared August 1, 2014:

"Plans are underway to bring back the two American aid workers sick with Ebola from Africa. A small private jet based in Atlanta has been dispatched to Liberia where the two Americans work for missionary groups. At least one of the Americans is expected to be treated in the U.S. at Atlanta's Emory University Hospital, which has a special isolation unit. **The hospital declined to identify the patient, citing privacy laws.** The private jet can only accommodate one patient at a time. In a press conference Friday afternoon, Emory's Dr. Bruce Ribner, said the facility had been informed that two patients were coming to the facility; one in a few days, the next a few days after that.." [Edited with highlight]

It was assumed that the "privacy laws" referenced were the HIPAA regulations related to the privacy and security of individually identifiable health information that was protected health information (PHI).

Clearly the decision to refuse identification was made, but was such a decision required?

1. The refusal was required since the request for identity was not being made by law enforcement which is the only way a disclosure of protected health information without authorization by the patient might be made under current regulations.

2. The disclosure might have been made, but refusal was now required since the US State Department

had made a format public statement that safety and security measures were being undertaken for the infected patient and the statement must be followed unless hospital regulations are more stringent.

3. The refusal decision was not required since the hospital as a covered entity (CE) could have disclosed, if consistent with law, the patient PHI if it had believed the disclosure would have in some way prevented an imminent threat to public health.

4. The refusal was required due to failure of the news agency to submit an appropriate authorization for disclosure outlining specifically the information type, scope, and limitations desired.

Answer: 3

Question 2 A medical practice received a request from a law enforcement official for information related to a patient of the practice. The unidentified law enforcement official made the request in person at the medical office for all of the patient's medical records saying that the request was for the purpose of general information in locating a missing person and that the patient was not the victim of a crime.

1. The information need not be provided since the practice is allowed 90 days for the provision of requested medical information and the determination of fee for provision on a "reasonable cost basis".

2. The request can be honored if the requesting law enforcement official is adequately identified since the request is from a governmental entity and has been made in person as opposed to electronic e.g. phone or Email.

3. The information cannot be provided since the only recognized method is that of an authorized subpoena from a court of competent jurisdiction for the medical practice.

4. The request should not be honored since any person requesting health information must be identified, the request was not a request pursuant to process or otherwise required by law, and the information must be specific and limited in scope to allowed information.

Answer: 4

1 Stobbe M. US Aiding Transfer of American Sick with Ebola. AP/Yahoo News. Site: www.news.yahoo.com. <http://news.yahoo.com/us-aiding-transfer-americans-sick-ebola-171012582.html>. Pub. August 1, 2014. Accessed October 11, 2014.



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