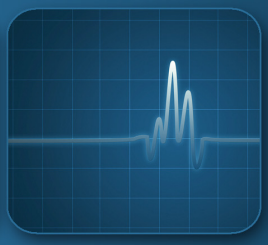
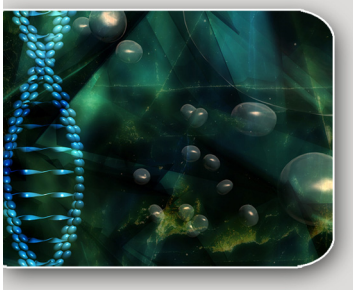
Polsinelli Shughart


HEALTH CARE LAW IN THE NEWS

February 2013



Uses and Disclosures of PHI under the Final Rule:

Changes Related to Marketing, Research, Fundraising and the Sale of Protected Health Information and Other Significant Changes

Breaking Down the HIPAA Changes: Part 4 of our 5-Part Series

The final HIPAA omnibus rule published in the *Federal Register* on January 25, 2013, (the Final Rule) made changes to how a Covered Entity (and its Business Associates) may use and disclose protected health information (PHI)—specifically uses and disclosures of PHI for marketing, fundraising, and research purposes. The Final Rule also included a prohibition on the sale of PHI and other modifications related to the use and disclosure of a decedent's PHI and disclosures of immunization records to schools.

The purpose of this e-alert is to provide an overview of (i) the Final Rule's modifications to the definition of marketing and how PHI may be used and disclosed for marketing purposes; (ii) the Final Rule's modifications to the requirements related to using PHI for research purposes; (iii) the Final Rule's modifications to the use of PHI for fundraising purposes; (iv) the Final Rule's prohibition on the sale of PHI; and (v) other miscellaneous modifications made by the Final Rule related to the use and disclosure of PHI of decedents and the disclosure of immunization records to schools.

I. Modifications Related to the Use and Disclosure of PHI for Marketing Purposes

The Final Rule modified how PHI is permitted to be used by a Covered Entity or a Business Associate for marketing purposes, mainly by modifying the definition of the types of activities that constitute "marketing" for purposes of HIPAA.

Under the Final Rule, if a Covered Entity receives financial remuneration in exchange for making a communication about a health-related product or service, the communication is considered marketing and the Covered Entity must obtain the individual's valid authorization, which includes a disclosure that the Covered Entity (or Business Associate) is receiving financial remuneration from a third party for making the communication—prior to actually making the communication. Previously, if such a communication were made for treatment or health care operations activities, such communications were excluded from the definition of "marketing." The United States Department of Health and Human Services (HHS) explained that this modification was made because of the difficulty in differentiating between communications that are for treatment or health care operations activities and other communications.

HHS clarified that remuneration related to marketing communications must be from or on behalf of the entity whose product or service is being described and in exchange for making the communication itself. Further, HHS noted that even where the Business Associate, rather than the Covered Entity, receives the financial remuneration, the communication is a marketing communication for which prior authorization is required.

Pursuant to the Final Rule, the following types of communications are expressly excluded from the definition of "marketing," and therefore, do not require an individual's authorization:

- Communications for treatment or health care operations activities that are made face-to-face, even if a Covered Entity receives financial remuneration for making the communication or the communication consists of a promotional gift of nominal value provided by the Covered Entity. Note: Communications that are made over the telephone are not considered face-to-face communications.
- Refill reminders or other communications about a drug or biologic that is currently prescribed for the individual, provided that any financial remuneration a Covered Entity receives for making such a communication is reasonably related to the Covered Entity's cost of making the communication (e.g., costs for labor, supplies, and postage). Note: This exclusion includes communications about the generic equivalent of a drug being prescribed to an individual, as well as adherence communications encouraging individuals to take their prescribed medications as directed.
- Communications promoting health in general that do not promote a product or service from a particular provider.
- Communications about government and government -sponsored programs.

Due to these changes, many arrangements that are in place today need to be evaluated and may need to be restructured (i.e., patient authorizations may need to be obtained) or the activities stopped all together prior to September 23, 2013.

II. Modifications Related to the Use and Disclosure of PHI for Research Purposes

In the Final Rule HHS addressed concerns expressed by the research community regarding the use of compound authorizations and also the presumed limitation on an individual's authorization allowing PHI to be used for future research.

A. Compound Authorizations Permitted

The Final Rule modifies the prohibition on using compound authorizations (i.e., where an authorization for the use and disclosure of PHI is combined with any other legal permission) for research activities that condition research-related treatment upon the signing of the authorization (conditioned research) with another authorization for research or a secondary activity related to research, such as bio-specimen banking, that does not condition treatment upon the signing of an authorization (unconditioned research). Under the Final Rule, a Covered Entity may utilize a compound authorization for conditioned and unconditioned research, except to the extent the research involves psychotherapy notes. In such instances the authorization must clearly differentiate between the conditioned and unconditioned research components and must clearly allow the individual the option to opt-into the unconditioned research activities (an opt-out provision is not permitted because such provisions do not provide individuals with a clear ability to authorize the unconditioned research activity and may be viewed as coercive).

Such permissible use of compound authorizations for research activities does not apply to research activities that involve the use or disclosure of psychotherapy notes. Any research activity involving the use or disclosure of psychotherapy notes must be accompanied by an authorization for such use or disclosure and can only be combined with another authorization for the use or disclosure of psychotherapy notes.

B. Authorizations for Future Research Permitted

Historically, HHS has interpreted the HIPAA Privacy Rule as requiring authorizations to be research study specific as part of the requirement that the authorization clearly identify the purpose of the authorized use or disclosure. The Final Rule modifies this historical interpretation and permits application of the authorization to uses and disclosures for future research; however, the authorization must still meet all of the core elements required to be in the authorization by the Privacy Rule, including an expiration date or event (e.g., "end of research study" or "none"), and the authorization must adequately describe the purpose in the authorization such that the individual understands that his or her PHI could be used or disclosed for future research activities.

The Final Rule does not prescribe what a future research activity description must include, but rather, leaves such determination to researchers and Institutional Review Boards. Because these changes related to

research activities expand an entity's ability to use or disclose PHI, no action is required by an entity to comply with the Final Rule. Note: The modifications made by the Final Rule do not prohibit Covered Entities from obtaining individual authorizations for use or disclosure of PHI for future research activities or for conditioned and unconditioned research, but rather make such a practice permissible.

III. Modifications Related to the Use of PHI for Fundraising Purposes

A. Opportunity to Opt-Out of Communications

The Final Rule added a requirement that if a Covered Entity, its institutionally related foundation, or a Business Associate on behalf of a Covered Entity, uses an individual's PHI for purposes of raising funds for the Covered Entity, the recipient of the communication must be provided with a clear and conspicuous opportunity to opt-out of receiving any further fundraising communications. Then, if an individual chooses to opt-out of receiving future fundraising communications, the Covered Entity must treat the individual's choice to opt-out as a revocation of the individual's authorization to use his or her PHI for fundraising communication purposes. This requirement applies equally to fundraising communications made in writing and to those made over the telephone. Note: This requirement applies only if an individual's PHI is used to make the communication, not merely if a communication is made. For instance, if a Covered Entity uses a public directory to mail communications to all residents in a particular geography, the requirement that the individual be provided with an opt-out option does not apply.

The Final Rule leaves the method for giving the individual the opt-out option up to the Covered Entity; however, the Final Rule specifies that the opt-out process may not cause the individual to incur undue burden or more than nominal cost. Examples of acceptable opt-out methods include: use of toll-free phone numbers, email addresses, or similar mechanisms. HHS does provide that requiring an individual to write a letter to opt-out would be considered an undue burden on the individual; however, requiring that an individual opt-out by simply mailing in a pre-printed, pre-paid postcard would not constitute an undue burden.

These modifications made by the Final Rule mean that Covered Entities must take the following actions / have the following procedures in place related to using an individual's PHI to make fundraising communications:

- The Covered Entity must have a data management system and process in place which enables the Covered Entity to track and flag those individuals that have opted-out of receiving fundraising communications in order to ensure that such individuals are not sent future communications.
- The Covered Entity must include in its Notice of Privacy Practices that it intends to contact the individual to raise funds and that the individual has the right to opt-out of receiving such communications.
- The Covered Entity must ensure that it does not condition treatment or payment on an individual's choice with respect to receiving fundraising communications.

Note: The Final Rule does not require that a Covered Entity send out pre-solicitation opt-outs prior to making the first fundraising communication.

B. Expanded Types of PHI Permissibly Used For Fundraising Communications

The Final Rule reiterates that demographic information, including names, addresses, other contact information, age, insurance status and gender can be used for fundraising communications. The Final Rule also includes date of birth in the acceptable types of demographic information that may be used to make a fundraising communication. Now, under the Final Rule, a Covered Entity may also use department of service information (e.g., cardiology, oncology, or pediatrics), treating physician information, and outcome information (e.g., sub-optimal results and death of the patient) in making fundraising communications. For instance, a hospital that is fundraising for its new cancer center may use oncology department PHI to target fundraising communications to former patients.

The Final Rule does, however, emphasize that when using PHI to make fundraising communications, the minimum necessary standard still applies and only the minimum amount of PHI necessary to accomplish the intended purpose may be used or disclosed.

IV. The Prohibition on the Sale of PHI

Under the Final Rule, a Covered Entity or Business Associate may only receive direct or indirect remuneration in exchange for the disclosure of PHI if the individual's authorization is obtained and the authorization states that the Covered Entity is receiving direct or indirect remuneration in exchange for the PHI or a relevant exception applies.

The Final Rule defines "sale of protected health information" as a disclosure of PHI by a Covered Entity or Business Associate, if applicable, where the Covered Entity or Business Associate directly or indirectly receives remuneration from or on behalf of the recipient of the PHI in exchange for the PHI. A sale of PHI is not limited to only those instances where there is a transfer of ownership of the PHI, but also includes remuneration for access, license, or lease agreements related to PHI. Sale of PHI includes any receipt of remuneration, including nonfinancial remuneration, but the remuneration must be directly for the PHI (or access thereto) and not related to a service involving access to the PHI. For instance, the Final Rule clarified that the fees paid by a Covered Entity for participation in a health information exchange (HIE) is for the services provided by the HIE and not for the PHI itself. Additionally, the prohibition on the sale of PHI does not apply to health information that has been de-identified in accordance with the Privacy Rule because such information is not considered PHI.

There are a handful of exceptions to the prohibition on the sale of PHI, including:

- For public health activities (including in limited data set form). Note: The remuneration for public health activities is not required to be cost-based.
- For treatment of the individual and payment.
- For the sale, transfer, merger or consolidation of all or part of a Covered Entity and for related due diligence purposes if the recipient of the PHI is or will become a Covered Entity following the sale, transfer or merger.

- For research purposes, if the remuneration is cost-based (including information in limited data set form).
- For services rendered by a Business Associate pursuant to a Business Associate Agreement at the specific request of the Covered Entity, provided that the remuneration is cost-based. For example, Business Associates may recoup fees from third party record requestors for preparing and transmitting records on behalf of a Covered Entity, to the extent such fees are reasonable, cost-based fees to cover the cost of preparing and transmitting the PHI. This exception also covers any remuneration paid by a Business Associate to its subcontractor for activities performed by the subcontractor on behalf of the Business Associate.
- For providing an individual with access to his or her PHI, including the provision of an accounting of disclosures.
- As required by law.

As it applies to the aforementioned exceptions, cost-based remuneration includes both direct and indirect costs (including labor, materials, and supplies for generating, storing, retrieving, and transmitting the PHI), labor and supplies to ensure the PHI is disclosed in a permissible manner, and overhead costs.

V. Other Modifications to the Privacy Rule Related to the Use and Disclosure of PHI

A. Use and Disclosure of a Decedent's PHI

The Final Rule modified the definition of PHI to exclude individually identifiable health information of persons who have been deceased for more than 50 years. As such, a person may use or disclose the PHI of a deceased individual for any purpose, provided that such individual has been deceased for more than a period of 50 years, unless state or other laws provide otherwise. The Final Rule clarified that this change is not reflective of a record retention requirement.

Under the Final Rule, disclosures of a decedent's PHI may be made to family members and others who were involved in an individual's care, unless doing so is inconsistent with any prior expressed wishes or preferences of the individual. Such revisions made by the Final Rule do not change the authority of a decedent's personal representative with regard to the decedent's PHI.

B. Disclosure of Immunization Records to Schools

Under the Final Rule, a Covered Entity may disclose proof of immunizations to schools in states that have laws that require the school to have such information prior to admitting a student. While written authorization for the disclosure is not required, Covered Entities are encouraged to obtain written or oral agreement from a parent, guardian, or other person acting in loco parentis for the individual, or from the individual himself or herself, if the individual is an adult or emancipated minor.

To conclude, the revisions to the HIPAA Privacy Rule resulting from the Final Rule that are related to the use and disclosure of PHI for marketing, research, and fundraising purposes, and the prohibition on the sale of

PHI are all very fact and circumstance specific. To determine how and to the extent such modifications will affect the operations of a Covered Entity or Business Associate, all arrangements that potentially implicate such requirements should be reviewed and modified for compliance purposes prior to September 23, 2013.

For More Information

For any questions on the topics covered in this Alert, please contact:

- Tom O'Donnell at todonnell@polsinelli.com or (816) 360-4173
- Erin Dunlap at edunlap@polsinelli.com or (314) 622-6661
- Rebecca Frigy at rfrigy@polsinelli.com or (314) 889-7013
- Matt Murer at mmurer@polsinelli.com or (312) 873-3603
- Emily Wey at ewey@polsinelli.com or (303) 583-8255

Matthew J. Murer
Practice Area Chair
Chicago
312.873.3603
mmurer@polsinelli.com

Colleen M. Faddick
Practice Area Vice-Chair
Denver
303.583.8201
cfaddick@polsinelli.com

Bruce A. Johnson
Practice Area Vice-Chair
Denver
303.583.8203
brucejohnson@polsinelli.com

Alan K. Parver
Practice Area Vice-Chair
Washington, D.C.
202.626.8306
aparver@polsinelli.com

Janice A. Anderson
Chicago
312.873.3623
janderson@polsinelli.com

Douglas K. Anning
Kansas City
816.360.4188
danning@polsinelli.com

Jane E. Arnold
St. Louis
314.622.6687
jarnold@polsinelli.com

Jack M. Beal
Kansas City
816.360.4216
jbeal@polsinelli.com

Cynthia E. Berry
Washington, D.C.
202.626.8333
ceberry@polsinelli.com

Mary Beth Blake
Kansas City
816.360.4284
mblake@polsinelli.com

Gerald W. Brenneman
Kansas City
816.360.4221
gbrenneman@polsinelli.com

Teresa A. Brooks
Washington, D.C.
202.626.8304
tbrooks@polsinelli.com

Jared O. Brooner
St. Joseph
816.364.2117
jbrooner@polsinelli.com

Anika D. Clifton
Denver
303.583.8275
aclifton@polsinelli.com

Anne M. Cooper
Chicago
312.873.3606
acooper@polsinelli.com

Lauren P. DeSantis-Then
Washington, D.C.
202.626.8323
ldesantis@polsinelli.com

S. Jay Dobbs
St. Louis
314.552.6847
jdobbs@polsinelli.com

Thomas M. Donohoe
Denver
303.583.8257
tdonohoe@polsinelli.com

Cavan K. Doyle
Chicago
312.873.3685
cdoyle@polsinelli.com

Meredith A. Duncan
Chicago
312.873.3602
mduncan@polsinelli.com

Erin Fleming Dunlap
St. Louis
314.622.6661
edunlap@polsinelli.com

Fredric J. Entin
Chicago
312.873.3601
fentin@polsinelli.com

Jennifer L. Evans
Denver
303.583.8211
jevans@polsinelli.com

T. Jeffrey Fitzgerald
Denver
303.583.8205
jfitzgerald@polsinelli.com

Michael T. Flood
Washington, D.C.
202.626.8633
mflood@polsinelli.com

Kara M. Friedman
Chicago
312.873.3639
kfriedman@polsinelli.com

Rebecca L. Frigy
St. Louis
314.889.7013
rfrigy@polsinelli.com

Asher D. Funk
Chicago
312.873.3635
afunk@polsinelli.com

Randy S. Gerber
St. Louis
314.889.7038
rgerber@polsinelli.com

Mark H. Goran
St. Louis
314.622.6686
mgroan@polsinelli.com

Linas J. Grikis
Chicago
312.873.2946
lgrikis@polsinelli.com

Lauren Z. Groebe
Kansas City
816.572.4588
lgroebe@polsinelli.com

Brett B. Heger
Dallas
314.622.6664
bheger@polsinelli.com

Jonathan K. Henderson
Dallas
214.397.0016
jhenderson@polsinelli.com

Margaret H. Hillman
St. Louis
314.622.6663
mhillman@polsinelli.com

Jay M. Howard
Kansas City
816.360.4202
jhoward@polsinelli.com

Cullin B. Hughes
Kansas City
816.360.4121
chughes@polsinelli.com

Sara V. Iams
Washington, D.C.
202.626.8361
siams@polsinelli.com

George Jackson, III
Chicago
312.873.3657
gjackson@polsinelli.com

Lindsay R. Kessler
Chicago
312.873.2984
lkessler@polsinelli.com

Joan B. Killgore
St. Louis
314.889.7008
jkillgore@polsinelli.com

Anne. L. Kleindienst
Phoenix
602.650.2392
akleindienst@polsinelli.com

Chad K. Knight
Dallas
214.397.0017
cknight@polsinelli.com

Sara R. Kocher
St. Louis
314.889.7081
skocher@polsinelli.com

Dana M. Lach
Chicago
312.873.2993
dlach@polsinelli.com

Jason T. Lundy
Chicago
312.873.3604
jlundy@polsinelli.com

Ryan M. McAteer
Los Angeles
310.203.5368
rmcateer@polsinelli.com

Jane K. McCahill
Chicago
312.873.3607
jmccahill@polsinelli.com

Ann C. McCullough
Denver
303.583.8202
amccullough@polsinelli.com

Ryan J. Mize
Kansas City
816.572.4441
rmize@polsinelli.com

Aileen T. Murphy
Denver
303.583.8210
amurphy@polsinelli.com

Hannah L. Neshek
Chicago
312.873.3671
hneshek@polsinelli.com

Gerald A. Niederman
Denver
303.583.8204
gniederman@polsinelli.com

Edward F. Novak
Phoenix
602.650.2020
enovak@polsinelli.com

Thomas P. O'Donnell
Kansas City
816.360.4173
todonnell@polsinelli.com

Aaron E. Perry
Chicago
312.873.3683
aperry@polsinelli.com

Mitchell D. Raup
Washington, D.C.
202.626.8352
mraup@polsinelli.com

Daniel S. Reinberg
Chicago
312.873.3636
dreinberg@polsinelli.com

Donna J. Ruzicka
St. Louis
314.622.6660
druzicka@polsinelli.com

Charles P. Sheets
Chicago
312.873.3605
csheets@polsinelli.com

Kathryn M. Stalmack
Chicago
312.873.3608
kstalmack@polsinelli.com

Leah Mendelsohn Stone
Washington, D.C.
202.626.8329
lstone@polsinelli.com

Chad C. Stout
Kansas City
816.572.4479
cstout@polsinelli.com

Steven K. Stranne
Washington, D.C.
202.626.8313
sstranne@polsinelli.com

William E. Swart
Dallas
214.397.0015
bswart@polsinelli.com

Tennille A. Syrstad
Denver
312.873.3661
etremmel@polsinelli.com

Emily C. Tremmel
Chicago
303.583.8263
tysrstad@polsinelli.com

Andrew B. Turk
Phoenix
602.650.2097
abturk@polsinelli.com

Joseph T. Van Leer
Chicago
312.873.3665
jvanleer@polsinelli.com

Andrew J. Voss
St. Louis
314.622.6673
avoss@polsinelli.com

Joshua M. Weaver
Dallas
214.661.5514
jweaver@polsinelli.com

Emily Wey
Denver
303.583.8255
ewey@polsinelli.com

Mark R. Woodbury
St. Joseph
816.364.2117
mwoodbury@polsinelli.com

Janet E. Zeigler
Chicago
312.873.3679
jzeigler@polsinelli.com

Additional Health Care Professionals

Julius W. Hobson, Jr.
Washington, D.C.
202.626.8354
jhobson@polsinelli.com

Harry Sporidis
Washington, D.C.
202.626.8349
hsporidis@polsinelli.com

About Polsinelli Shughart's
Health Care Group

The Health Care group has vast national resources and strong Washington, D.C. connections. With highly trained, regulatory-experienced attorneys practicing health care law in offices across the country, we are familiar with the full range of hospital -physician lifecycle and business issues confronting hospitals today. A mix of talented, bright, young attorneys and seasoned attorneys, well known in the health care industry, make up our robust health care team.

Polsinelli Shughart is the 10th largest health care law firm in the nation, according to the 2010 rankings from Modern Healthcare magazine. The publication annually ranks law firms based on their total membership in the American Health Lawyers Association. With one of the fastest-growing health care practices in the nation, Polsinelli Shughart has the depth and experience to provide a broad spectrum of health care law services.

About
Polsinelli Shughart

Serving corporations, institutions, entrepreneurs, and individuals, our attorneys build enduring relationships by providing legal counsel informed by business insight to help clients achieve their objectives. This commitment to our clients' businesses has helped us become the fastest-growing, full-service law firm in America*. With more than 600 attorneys in 16 cities, our national law firm is a recognized leader in the industries driving our growth, including healthcare, financial services, real estate, life sciences and technology, energy and business litigation. The firm can be found online at www.polsinelli.com. Polsinelli Shughart PC. In California, Polsinelli Shughart LLP.

**Inc.* Magazine, September 2012

About
This Publication

If you know of anyone who you believe would like to receive our e-mail updates, or if you would like to be removed from our e-distribution list, please contact us via e-mail at Interaction@polsinelli.com.

Polsinelli Shughart provides this material for informational purposes only. The material provided herein is general and is not intended to be legal advice. Nothing herein should be relied upon or used without consulting a lawyer to consider your specific circumstances, possible changes to applicable laws, rules and regulations and other legal issues. Receipt of this material does not establish an attorney-client relationship.

Polsinelli Shughart is very proud of the results we obtain for our clients, but you should know that past results do not guarantee future results; that every case is different and must be judged on its own merits; and that the choice of a lawyer is an important decision and should not be based solely upon advertisements.

Polsinelli Shughart PC. In California, Polsinelli Shughart LLP.

Polsinelli Shughart® is a registered trademark of Polsinelli Shughart PC.