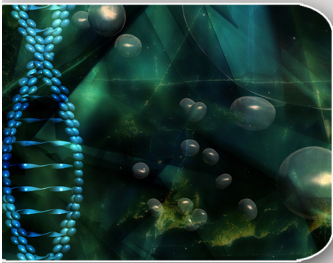




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## Changes to Patients' Rights Under the Final Rule

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

The final HIPAA omnibus rule published in the *Federal Register* on January 25, 2013, (the Final Rule) expands certain individual rights, including the right to access protected health information (PHI) maintained electronically and the right to restrict disclosures to health plans when paying out of pocket. This e-alert discusses these changes in more detail and provides some guidance to Covered Entities on how to implement these changes by September 23 – the required compliance date.

### I. Right to Access Protected Health Information

Individuals currently have the right to review or obtain copies of their PHI,

to the extent such information is maintained in the designated record set(s) of a Covered Entity. The Health Information Technology for Economic and Clinical Health Act (HITECH Act) expanded this right of access to give patients the right to an electronic copy of PHI that is maintained in an electronic health record (EHR), and the Final Rule took that right one step further – to apply to all designated record sets maintained electronically.

Under the Final Rule, if an individual requests an electronic copy of PHI that is maintained electronically in one or more designated record sets, the Covered Entity must provide the individual with access to the electronic information in the electronic form or format requested by the individual, if it is readily producible in the requested

form or format. If the PHI is not maintained in the requested form or format, the entity must provide the individual with the PHI in a readable electronic form and format agreed to by both parties, e.g., providing a disc with a PDF file, sending a secure email with a Word file or providing access through a secure web-based portal. A hard copy may be provided if the requesting individual rejects all of the offered electronic formats.

HHS further clarified: (i) a Covered Entity is not required to provide individuals with direct access to their systems; (ii) if the designated record set contains electronic links to images or data, the images or other data must be included in the electronic copy provided; (iii) if a medical record is in mixed media (e.g., some paper and some electronic), a Covered Entity is not required to scan the paper documents to provide a single electronic copy – a combination of electronic and hard copies may be provided; (iv) a Covered Entity is not required to use an individual's flash drive or other device to transfer the electronic PHI if the Covered Entity has security concerns regarding the external portable media; and (v) a Covered Entity may send individuals unencrypted emails if it has notified the individual that there may be some level of risk that the information could be read by a third party, and the individual still prefers the unencrypted email.

Under the Final Rule, if requested by an individual, a Covered Entity must transmit the electronic copy of PHI directly to another person designated by the individual. However, the designation must be in writing, signed by the individual, and clearly identify the designated person as well as where to send the copy of the PHI. Note: This written request for PHI to be sent to a designated person is distinct from the authorization form, which contains many additional required statements and elements.

Covered Entities must act on an individual's request for access to his or her own PHI, whether paper or electronic, within 30 days following receipt of the request; however, they may have a one-time extension of up to 30 days upon provision of written notice to the individual (within the original 30-day time frame), and the notice must include

the reason for the delay and the expected date of completion. Significantly, under the Final Rule, the fact that PHI is maintained off-site will no longer warrant an additional 30-day extension. HHS expects Covered Entities who maintain PHI off-site to comply within 30 days of the request – or within 60 days if they provide written notice to the individual, as described above. These are the outer limits for responding to requests for access to PHI; HHS encourages Covered Entities to provide individuals with access to their information sooner and to take advantage of technologies that provide individuals with immediate access to their PHI.

The Final Rule also modified what may be included in the reasonable, cost-based fees that may be charged to individuals when providing them copies of their PHI. Under the Final Rule, labor costs for copying PHI, whether in paper or electronic form, may be included in a reasonable cost-based fee. These labor costs may include technical staff time spent to create and copy the electronic file, such as compiling, extracting, scanning and burning PHI to media. Reasonable, cost-based fees may also include: (i) the cost of supplies for creating electronic media (e.g., discs, flash drives, etc.); and (ii) the cost of postage if the individual requests that the portable media be sent by mail or courier. However, under the Final Rule, Covered Entities may not include: (i) costs of new technology, maintaining systems for electronic PHI, data access and storage infrastructure; or (ii) a retrieval fee (whether standard or actual costs) for



electronic copies. Note: If costs permitted under HIPAA exceed the state law limits, the Covered Entity may not charge more than the state law allows.

## II. Restrictions on Health Plan Disclosures

Under the Final Rule, Covered Entities are required to comply with an individual's request to restrict disclosures of PHI to a health plan if (i) the disclosure is for the purpose of carrying out payment or health care operations, and is not otherwise required by law, and (ii) the PHI pertains solely to a health care item or service for which the individual, or a person acting on behalf of the individual (other than the health plan), has paid the Covered Entity in full.

A number of concerns were raised in the rule-making process about implementing these required restrictions. In response, HHS clarified:

- Providers are not required to create separate medical records or otherwise segregate PHI subject to a restricted health care item or service. However, they will need to flag or use some other method to identify portions of the record that contain PHI subject to a required restriction to ensure it is not inadvertently sent or made accessible to the health plan for payment or healthcare operations purposes (e.g., audits by the health plan);
- Providers are not required to abide by a required restriction if a patient's payment is dishonored. However, providers should make reasonable attempts to resolve payment issues with the patient prior to disclosing PHI to the health plan. Alternatively, a provider may require payment in full at the time the restriction is requested.
- To the extent a patient requests a restriction with respect to one of several items or services provided in a single patient encounter, the provider should counsel the patient on the ability or inability of the provider to unbundle the items or services and the impact of doing so (e.g., the health plan still may be able to determine the services performed based on the context). If the provider cannot unbundle the items or services, the provider should inform the patient and give the patient the option to restrict and pay out of pocket for the entire bundle of items or services.
- The obligation to notify downstream health care providers of restrictions on the disclosure of PHI falls on the patient – not the provider. HHS believes it would be unworkable at this point, given the lack of automated technologies to support such a requirement, to require health care providers to notify downstream providers of the fact that an individual has requested a restriction on the disclosure of PHI to a health plan.
- If the patient does not request a restriction and pay out of pocket for follow-up treatment, the provider may include previously restricted PHI when billing the health plan for the follow-up treatment – if necessary to have such a service deemed medically necessary.
- Contractual requirements for a provider to submit claims to a health maintenance organization (HMO) do not exempt the provider from his or her obligations with respect to the required restrictions. Note: Provider contracts may need to be updated to be consistent with these new requirements.



### III. Guidance on How to Comply With the Expanded Patient Rights

In response to these changes in the Final Rule, Covered Entities should consider the following actions:

1. **Evaluate Electronic Systems** A Covered Entity should evaluate its current electronic system to determine (i) if it maintains PHI electronically in one or more designated record sets and, if so, can it provide copies of the PHI in a readable electronic format; and (ii) if information subject to a required restriction can be flagged or segregated in the system to ensure the information is not disclosed to health plans. Some Covered Entities may need to invest in upgraded systems in order to meet these requirements.
2. **Revise Notice of Privacy Practices (NPP)** As discussed in the first e-alert in this series, a Covered Entity may need to revise its NPP to incorporate these new individual rights – as well as other changes under the Final Rule. For example, a health care provider’s NPP must now include a specific statement that individuals have a right to restrict certain disclosures of PHI to a health plan where the individual pays out of pocket in full for the health care item or service.
3. **Review and Revise Policies and Procedures** A Covered Entity should review and modify its policies and procedures to incorporate these expanded individual rights. For example, a Covered Entity must implement reasonable policies and procedures to verify the identity of any person who requests PHI and a Covered Entity must determine the process by which its workforce members are going to “flag” data that is subject to a required restriction.
4. **Train Workforce Members** A Covered Entity should identify workforce members whose job functions will be affected by the Final Rule and train those workforce members in implementing these expanded individual rights. ■

### For More Information

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



- Kristen Rosati, *President-Elect of the American Health Lawyers Association* at [krosati@polsinelli.com](mailto:krosati@polsinelli.com) or (602) 650-2003
- Tom O'Donnell at [todonnell@polsinelli.com](mailto:todonnell@polsinelli.com) or (816) 360-4173
- Erin Dunlap at [edunlap@polsinelli.com](mailto:edunlap@polsinelli.com) or (314) 622-6661
- Rebecca Frigy at [rfrigy@polsinelli.com](mailto:rfrigy@polsinelli.com) or (314) 889-7013
- Matt Murer at [mmurer@polsinelli.com](mailto:mmurer@polsinelli.com) or (312) 873-3603
- Emily Wey at [ewey@polsinelli.com](mailto: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

Linus 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  
816.622.6663  
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

Kristen B. Rosati  
Phoenix  
602.650.2003  
krosati@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

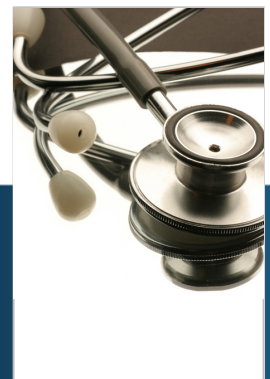
Mark R. Woodbury  
St. Joseph  
816.364.2117  
mwoodbury@polsinelli.com

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





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