



# 5<sup>th</sup> Annual Meeting of PSOs

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## How to Assemble and Develop the Patient Safety Workforce

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GROWER **GK** KETCHAM



# Qualified Staff for the PSO

## Criteria for the initial and subsequent certification of a PSO:

- Mission & primary activity = improve patient safety & quality of health care
- ***The entity has appropriately qualified staff*** (whether directly or through contract), ***including licensed or certified medical professionals***
- Bona fide contracts with more than 1 provider
- Not a component of a health insurer
- Discloses financial relationships with providers
- Collects PSWP in a standardized manner that permits valid comparisons
- Provide direct feedback and assistance to providers to effectively minimize patient risk.



# *Appropriately* Qualified Staff

## **2ap·pro·pri·ate**

*adjective*

1: specially suitable : fit, proper <by any means *appropriate* to our use — George Meredith>

2: belonging peculiarly : special <the pupil lacks the qualities *appropriate* to the master's style — David Sylvester>

3 *obsolete*: attached as an accessory possession

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# *Appropriately* Qualified Staff

"*Appropriate*" is one of the most wonderful weasel words in the dictionary, and a great aid to the resolution of disputed issues in the drafting of legislation. Who, after all, can be found to stand up for "*inappropriate*" treatment or actions of any sort?

Cleland v. Bronson Health Care Group Inc., 917 F.2d 266 (6th Cir. 1990)

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# *Qualified Workforce*

- **Patient Safety Organizations: A Compliance Self-Assessment Guide**
    - <http://www.pso.ahrq.gov/listing/saguide.htm>
    - Use the **WHOLE** Guide
    - **HOW** to show PSO Workforce is “Qualified Workforce” is in Table 1  
<http://www.pso.ahrq.gov/listing/saguide2.htm#tab1>
    - **WHAT** that Workforce does is everywhere in the guide
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# *Appropriately* Qualified Staff

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**FAST FACTS** = Crib Notes

<http://www.pso.ahrq.gov/psos/fastfacts.htm#ff17>

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# *Appropriately* Qualified Staff

- **“Workforce”** = volunteers, employees, or contractors
  - **Direct control / supervision** of the PSO
  - **“*Medical*” experience will reflect the type of patient safety events reported to and analyzed by the PSO**
    - E.g., PSO analyzing only adverse drug events might have a pharmacist as a member of their workforce.
  - **Many specialties/skills** (do not all need same expertise)
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# Expertise?

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- All too often we convince ourselves that:
  - **An expert is a man fifty miles from home with a briefcase.**
    - Will Rogers
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***Expert-ise !***

**3ex·pert**

noun

**1:** one who has acquired **special skill** in or **knowledge** of a particular subject

**through professional training or practical experience** : authority, specialist

Webster's Third New International Dictionary, Unabridged, s.v. "expert," accessed March 19, 2013, <http://unabridged.merriam-webster.com>.

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# EXPERT –ise!

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- An **expert** is a person who has found out, by his own painful experience, all the mistakes that one can make in a very narrow field.
    - Neils Bohr, as quoted by Edward Teller, *LIFE Magazine* (6 September 1954)
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# Documenting use of Qualified

- Written policies for utilization of qualified staff (either as members of the PSO's workforce or as contractors)
  - Job descriptions for staff positions
    - “appropriate match” for the clinical, analytic, and improvement activities that the PSO offers
    - “reasonable relationship” between the expertise and skills of its medical professional(s) and the clinical issues the PSO addresses PSES Training
  - Background Check?
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# Documenting the *Qualifications* of Staff (Expertise)

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- Curriculum vitae
  - Job references
  - Published projects
  - Aptitude Testing?
  - Trial Employment/Contract
  - If possible, view previous work product
  - PSES Training and Agreements
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# Utilization of *Qualified* Staff

- 42 U.S.C. § 299b-21(5)(G)
- = ***ESSENTIAL*** “Patient Safety Activity”
- But what does it mean?
- “Qualified” by provider to render health care in a more safe manner?
  - Credentialing
  - Job descriptions
  - Training
- Or does it mean “Qualified” for the PSO work?



# Utilization of *Qualified Staff*

## ■ Context

“**patient safety work product**’ means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements-- which-- are developed by a PSO *for the conduct of patient safety activities*; and which could result in improved patient safety, health care quality, or health care outcomes

- Does PSO develop feedback *for providers* on “utilization of qualified staff”?
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# Utilization of *Qualified* Staff

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- Or does it mean staff that is “*qualified*” for analyzing patient safety work product at both levels – provider and PSO?
    - Analysis of Data
    - Job descriptions
    - Training
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# Utilization of *Qualified Staff*

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- **Patient Safety Rule** may clarify:

“The term '**patient safety activities**' means the following activities carried out by or on behalf of a **PSO** or a **provider**:

(7) Utilization of Qualified Staff

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# Workforce

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- Other Providers
  - Employed Staff
  - Volunteers
  - Contractors
  - Elected officials?
  - Affiliated Providers?
  - Borrowed Employees?
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# Workforce

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## *Responsible person*

- means a person, *other than a provider or a PSO*, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions.

## *Workforce*

- means employees, volunteers, trainees, contractors, or other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is *under the direct control of such provider*, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person.
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# Direct control

- **Workforce** must be under the *direct control* of principal
  - Because of the “direct control” language of the proposed rule, *all workforce members*, including those who are not employees, are agents of a principal.
  - Principal could be liable for violation by any workforce member acting within the scope of employment or agency.
  - **The determinative issue is whether**
    - **a person is sufficiently under the control of a person or entity and**
    - **acting within the scope of the agency.**
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# Control

- "Direct control" is NOT defined by Patient Safety Rule
  - But includes contractors
- *Compare* IRS "control" test for employees
  - Distinguishes between employees & contractors
- *Compare* SEC "control" test for securities violations
  - "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 C.F.R. § 230.405.



# Control

- "Agency is a legal concept which depends upon the existence of required factual elements: the manifestation by the principal that the agent shall act for him, the agent's acceptance of the undertaking and the understanding of the parties that the principal is to be in control of the undertaking."
    - Restatement (Second) of Agency § 1 cmt. b (1958).
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# Control

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**Principal/agency relationship** requires:

- **control** (or the right to direct or control)
  - **manifestation of consent** by one person to another that the other shall act on his behalf and
  - **consent** by the other so to act.
    - Restatement (Second) of Agency § 1 , cited with approval in *Meyer v. Holley*, 537 US 280 (2003).
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# Control

- “Federal Common Law Employment Test”
  - Thirteen (13) non-exhaustive factors
    - Community for Creative Non-Violence v. Reid, 490 U.S. 730 (1989)
    - Nationwide Mut. Ins. Co. v. Darden, 503 U.S. 918 (1992)
    - “Right to control manner and means” is factor
  - Hybrid Test used in many Circuits
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# Contractors = Contracts

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- Don't forget other laws for contracts with health care entities
    - Stark
    - Antikickback
    - Inurement
    - HIPAA
    - Etc.
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## Fed. Reg. comments (Proposed Rule)

- Discussing PSWP with or providing PSWP to a **contractor** **under the direct control** of an entity (i.e., a workforce member) would be a **use** of the information within the entity and, therefore, not a disclosure for which a permission is needed.
- disclosure to an **independent** contractor would **not** be a use of the information by a workforce member, and thus, **would be a disclosure**



# *Disclosure Definition (1)*

**Disclosure** means

- Divulging PSWP
- To another *legally separate* entity or natural person, e.g.
  - Government Agency
  - Parent Corporation
  - Rest of Component (for a Component PSO)
- Check § 3.206 Disclosure Exceptions  
**CAREFULLY**



# *Disclosure Definition (2)*

**Disclosure** means

- Entity or natural person holding PSWP
- Divulges PSWP
- To another *legally separate* entity or natural person,
- **other than**
  - a *workforce member* of the entity **or**
  - a health care *provider* holding *privileges* with the entity holding the PSWP

Can credentialed providers also be “workforce” ?



# HIPAA interacts with PSQIA

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- **“Health care operations”**
    - Conducting **quality assessment and improvement activities**, *including* . . .
    - **patient safety activities**
      - (as defined in 42 C.F.R. § 3.20)
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# But PSQIA ≠ HIPAA

- **PSO = Business Associate**

## **BUT**

- **Provider for PSQIA ≠ Covered Entity**
- **Affiliated Provider for PSQIA ≠ OHCA**
  - (*"Organized Health Care Arrangement"*)



# HIPAA contract ≠ PSQIA contract

- “Sample” BAA Form
    - No “**direct control**” language
    - What **other indicia or evidence of control** can you use?
  - OHCA?
    - More than one “**provider**” under PSQIA?
  - Security and More (?) –
    - Warranty
    - Intellectual Property
    - Sub-contractors
    - Indemnity / Insurance / Data Logs and Backup
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# Questions

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