



4th Annual Meeting of PSOs

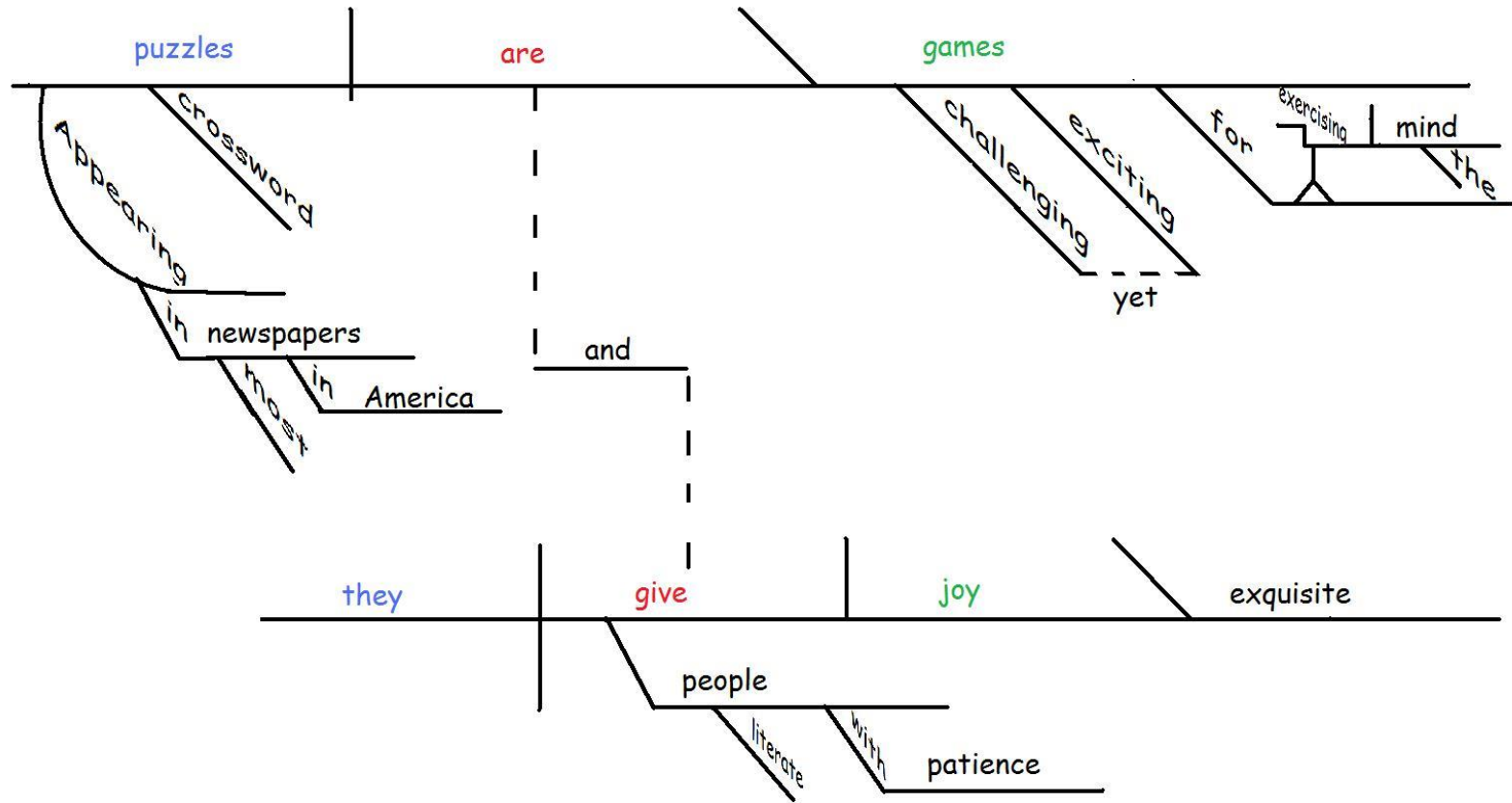
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Preparations and Prepositions:

A Grammar School Guide to Creating a PSES

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Parsing Patient Safety

Information created for and actually sent to a PSO

Information and analysis coming by (and coming back from) the PSO

Documentation of deliberations or analysis of, or the fact of reporting pursuant to, a patient safety evaluation system (e.g., minutes of meetings, other analyses)



Patient Safety Evaluation System

Definition

- “The collection, management, or analysis of information **for** reporting to the PSO”
 - Understanding this definition and building the processes for sending and receiving information is key to successful implementation
 - Defining the elements, creating the policies and developing the electronic transfer of validated data is also crucial to success
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Patient Safety Evaluation System

Means the

- Collection,
 - Management, or
 - Analysis
- **of** information
 - **for** reporting
 - **to** [a PSO] or
 - **by** a PSO.
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KEY DEFINITION: Patient Safety Work Product

Any data, reports, records, memoranda, analysis (such as root cause analysis), or written or oral statements which:

- **“Are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization,”**
- **“Are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes”**
- **“Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to a *patient safety evaluation system*.”**



In other words,
Patient Safety Work Product **is:**

- **Information created for and actually sent to a PSO**
 - **Information and analysis by a PSO (and often coming back from the PSO)**
 - **Documentation of the Patient Safety Evaluation System**
(e.g., minutes of meetings, other analyses)
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"for"

1 *obsolete* : before

2 a : as a preparation toward...or against ... or in view of <making plans *for* retirement> <studying *for* examinations>
: having as goal or object <volunteered *for* the air force> . . .

d : to supply the need of <food *for* hungry mouths> . . .

3 d : used as a function word to indicate the person or thing that something is to be delivered to <any letters *for* me> or assigned to <a slot *for* out-of-town mail> or used by or in connection with <are these the tires *for* this car> . . .

8 a : because of <shouted *for* joy> : on account of <decorated *for* bravery>
<do it *for* my sake>

Source: "for." Webster's Third New International Dictionary, Unabridged. Merriam-Webster, 2002.
<http://unabridged.merriam-webster.com> (21 Mar. 2012).



"to"

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- 1** -- used as a function word to indicate spatial relationships or relationships that suggest motion: as
- a** -- used as a function word to indicate movement or an action or condition suggestive of movement toward
- (1) : a place, person, or thing that is reached or is thought of as being reached <drove *to* the city> <ran *to* his mother>... <a trip *to* the moon>...
- 2** -- used as a function word to indicate purpose, intention, tendency, result, or end: as
- a** (1) : for the purpose of : with a view to : aiming at : **FOR** <came *to* our aid> <trained *to* a religious life>...

Source: "to." *Webster's Third New International Dictionary, Unabridged*. Merriam-Webster, 2002.
<http://unabridged.merriam-webster.com> (21 Mar. 2012).



"developed by . . ."

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- 1 a** : in proximity to : in the immediate neighborhood of -- used of place or position: ...
- 4 a** : through the means or instrumentality of <put to death *by* the sword>
b : through the direct agency of ... <a poem written *by* Keats>
c : through the medium of (an indirect or subordinate agent)
<represented *by* his deputy> <votes *by* proxy> ...
- f** : in consequence of : as a result of : through...
- g** -- used as a function word to indicate something that forms an accompanying setting or condition <ate *by* candlelight> or that constitutes a manner <began *by* criticizing the style of the poem> often with an added sense of means <the case went *by* default>

Source: "by." Webster's Third New International Dictionary, Unabridged. Merriam-Webster, 2002.
<http://unabridged.merriam-webster.com> (21 Mar. 2012).



“identify or constitute the deliberations or analysis of. . .”

- 1** *obsolete* -- used as a function word to indicate the place or thing from which anything moves, comes, goes, or is directed or impelled ...
- 7** -- used as a function word to indicate the agent or doer of an act or action ...
(3) after a noun indicating the maker or doer often with the force of a subjective genitive <plays *of* Shakespeare>...
- 11** : relating to : with reference to : as regards : **ABOUT** <stories *of* his travels> <the truth *of* the matter> <judge *of* the case> ...
- 12** -- used as a function word indicating the object of an action denoted or implied by the preceding noun <love *of* nature> <care *of* children> <creation *of* the world> ... <pursuit *of* happiness> <knowledge *of* the past>...
- 17 a** -- used as a function word indicating a possessive relationship <gates *of* heaven> <courage *of* the pioneers> ... -- used often with a following possessive <a friend *of* mine> <an acquaintance *of* the colonel's> ...



Patient safety work product does not include:

- Patient's medical record
- Billing and discharge information
- Any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists *separately*, from a *patient safety evaluation system*.



Separate(ly) from a PSES

- Information that is collected, maintained, or developed separately, or exists separately, from a *patient safety evaluation system*.

NOTE: If “separate information” or a copy thereof is reported to a PSO, it does **not** become patient safety work product.



§ 299b-22(g)-- Rule of construction

Nothing in this section shall be construed—

- (1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;
 - (2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section; . . .
 - (5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or
 - (6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.
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Exists Separately

QAPI / State Reporting	PSES
Incident reports, grievances	Discussions, common formats, root cause analysis
Action plans (patient safety plans, policies, etc.)	PSO Analysis, metrics, case-by-case reviews, meta-analysis



§ 299b-22(h) -- Clarification

Nothing in this part prohibits

- any person
 - from conducting **additional analysis**
 - for **any** purpose
 - regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a [PSO] or a [PSES].
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IDENTIFIABLE PATIENT SAFETY WORK PRODUCT

- identifies any provider that is a subject of the work product, or any **providers** that participated in the activities that are a subject of the work product
 - constitutes individually identifiable health information of **patients** (HIPAA)
 - identifies an **individual who reported information** to the PSO
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One Provider or Many?

Hospital

ACO partner

Doctor

Nurse



Workforce

- Employee
 - Contractor
 - Medical Staff
 - Affiliated Provider (?)
 - Board member (?)
 - Public Board Member (?)
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Permissible Disclosures

Accrediting Agencies
(TJC -DNV)

VS.

Quality Improvement Organizations



Jack Benny - Patient Safety Genius

It's All in the Timing?

-- Purported title of Johnny Carson's thesis on Comedy
at the University of Nebraska

Read more: <http://www.time.com/time/arts/article/0,8599,1020765,00.html#ixzz1podBViGA>



Removal and Time of Transmission?

Patient safety work product:

- (2)...(ii) Patient safety work product assembled or developed by a provider for reporting to a PSO may be removed from a patient safety evaluation system and no longer considered patient safety work product if:
 - (A) The information has not ***yet*** been reported to a PSO; and
 - (B) The provider documents the act and date of removal of such information from the patient safety evaluation system.

42 C.F.R. § 3.20 *Patient safety work product*



Unsettled issues

- **Will courts recognize removal of PSWP**
 - Not in PSQIA
 - **Administrative “nullification”?**
 - How far does 42 U.S.C. § 299b-22(g)(2) go?
 - How far does 42 U.S.C. § 299b-22(h) go?
 - **Future of PSOs in an ACO world**
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Questions

