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Patient Safety and Quality Improvement Act of 2005—HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations

Effective Date: May 24, 2016

Overview of the Guidance Document

Why Was The Guidance Issued?

- Clarify what information that a provider creates/assembles can become PSWP
- Help address conflicts between providers and CMS surveyors over PSWP
- Address concerns with how some providers may be using PSWP to meet their external obligations
- Address questions raised by the Tibbs case

Breaking Down the Guidance

The document has two main sections:

1. Background
2. Meeting External Obligations

~ Breaking Down the Guidance ~
Background

1. HHS Approach to Patient Safety Act Interpretation
2. How Information Becomes PSWP
3. Information That Is Not PSWP
4. Purpose for Which Information Was Assembled Or Developed

~ Breaking Down the Guidance ~
Meeting External Obligations

1. The Patient Safety Act Does Not Relieve a Provider From Its External Obligations
2. Original Patient and Provider Records
3. Copies of PSWP
4. Separate Systems
5. Shared Responsibility
6. Later Developing Requirements

Background

1. HHS Approach (1)

- "…the Patient Safety Act recognizes the goal of accountability and transparency, and it attempts to balance this goal with that of improving patient safety and reducing medical errors. "
- "The Patient Safety Act promotes the goal of improving patient safety and reducing medical errors by establishing a system in which health care providers can voluntarily collect and report information related to patient safety, health care quality, and health care outcomes to PSOs."
- "At the same time, providers are subject to legitimate external obligations regarding certain records about patient safety to ensure their accountability and transparency." (e.g. Medicare's Conditions of Participation, state health care regulators, tort system)

"The intent of the system established by the Patient Safety Act is to protect the ***additional*** information created through voluntary patient safety activities, not to protect records created through providers' mandatory information collection activities."

Background

1. HHS Approach (2)

- "It is not the intent of this legislation to establish a legal shield for information that is already currently collected or maintained separate from the new patient safety process, such as a patient's medical record. That is, information which is currently available to plaintiffs' attorneys or others will remain available just as it is today.'' 151 Cong. Rec. S8741 (daily ed. Jul. 22, 2005) Senator Enzi
- "Nor does this bill alter any existing rights or remedies available to injured patients. The bottom line is that this legislation neither strengthens nor weakens the existing system of tort and liability law.'' Id. Senator Jeffords
- "Nor was the Patient Safety Act intended to insulate providers from demonstrating accountability through fulfilling their external obligations."

Background

2. How Information Becomes PSWP (1)

The Guidance reviews the three pathways for information to become PSWP:

1. The information is prepared by a provider for reporting to a PSO and it is reported to the PSO;
2. The information is developed by a PSO for the conduct of patient safety activities; or
3. The information identifies or constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a patient safety evaluation system (PSES).

Background

2. How Information Becomes PSWP (2)

For information to become PSWP through the reporting pathway:

- Eligible information must be information that could improve patient safety, health care quality, or health care outcomes;
- Eligible information must meet the purpose requirement: it was assembled or developed *in a provider's PSES* for *the sole purpose of reporting* to a PSO and (ultimately*) is reported to a PSO*.

Note: A provider should only place information in its PSES if it intends to report that information to the PSO

Background

3. Information That Is Not PSWP (1)

Specifically excluded from the definition of PSWP is:

- "a patient's medical record, billing and discharge information, or any other original patient or provider information" and
- "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system."

Put another way, information prepared for purposes other than reporting to a PSO is not, itself, PSWP under the reporting pathway.

Background

4. Purpose For Which Information Is Assembled/Developed (1)

- Uncovering the purpose for which information is prepared can be a critical factor in determining whether the information is PSWP.

Some types of information may or may not be PSWP depending on why the information was assembled or developed.

Therefore, it is important for providers to be aware of whether or not information is prepared for the purpose of reporting to a PSO.

Background

4. Purpose For Which Information Is Assembled/Developed (2)

EXAMPLE – 1

Information related to functioning of medical equipment

Not PSWP If Prepared

For upkeep of equipment (e.g., original equipment maintenance logs), to maintain a warranty, or for an external obligation (e.g., CMS requires some equipment logs).

Could be PSWP if information is not required for another purpose and is prepared solely for reporting to a PSO

Following a patient incident, a provider develops information about possible equipment malfunctions for reporting to a PSO so that the PSO can aggregate it with other rare events from other reporting providers to identify risks and hazards.

Background

4. Purpose For Which Information Is Assembled/Developed (3)

EXAMPLE – 2

A list of provider staff who were present at the time a patient incident occurred

Not PSWP If Prepared

To ensure appropriate levels of clinician availability (e.g., routine personnel schedules), or for compliance purposes

Could be PSWP if information is not required for another purpose and is prepared solely for reporting to a PSO.

Following the incident, a provider originally assembles the list for reporting to a PSO so the PSO can analyze the levels and types of staff involved in medication errors.

~ Breaking Down the Guidance ~
Meeting External Obligations

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The Guidance: External Obligations

1. Patient Safety Act Does Not Relieve a Provider From Its External Obligations (1)

The Patient Safety Act definition of PSWP states:

"(iii)Nothing in this part shall be construed to limit—

…"(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

"(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

[underlining added for emphasis]

The Guidance: External Obligations

1. Patient Safety Act Does Not Relieve a Provider From Its External Obligations (2)

The Patient Safety Act further reinforces that the statute shall not be construed:

…"(2) to limit, alter or affect the requirements of Federal, State, or local law pertaining to information that is not" PSWP or

…"(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not" PSWP

[underline added for emphasis]

The Guidance: External Obligations

1. Patient Safety Act Does Not Relieve a Provider From Its External Obligations (3)

The Notice of Proposed Rulemaking (NPRM) ~

"…the statute is quite specific that these protections do not relieve a provider from its obligation to comply with other legal, regulatory, accreditation, licensure, or other accountability requirements that it would otherwise need to meet."

> "…the protected system established by the Patient Safety Act, resides alongside but does not replace other information collection activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system."

"…nothing in the final rule or the statute relieves a provider from his or her obligation to disclose information from such original records or other information that is not patient safety work product to comply with state reporting or other laws."

The Guidance: External Obligations

1. Patient Safety Act Does Not Relieve a Provider From Its External Obligations (4)

The BOTTOM LINE…

HHS reiterates that any external reporting or recordkeeping obligations — whether they require a provider to —

- report certain information,
- maintain specific records, or
- operate a separate system

— cannot be met with PSWP.

The Guidance: External Obligations

2. Original Records (1)

- The Act and Rule: Patient safety work product "does not include a patient's medical record, billing and discharge information, or any other original patient or provider information..." 42 U.S.C. 299b-21(7)(B)(i).
- HHS previously stated that information prepared for other purposes or obligations is not PSWP and provided the following examples of such information not eligible to become PSWP:
  - Information prepared for "internal risk management purposes or to fulfill external reporting obligations." (73 FR 8121); and
  - Information … collected to comply with external obligations, such as: state incident reporting requirements; adverse drug event information reporting to the Food and Drug Administration (FDA); certification or licensing records for compliance with health oversight agency requirements; reporting to the National Practitioner Data Bank of physician disciplinary actions; complying with required disclosures by particular providers or suppliers pursuant to Medicare's conditions of participation or conditions of coverage; or provision of access to records by Protection and Advocacy organizations as required by law." (73 FR 70742-70743).

The Guidance: External Obligations

2. Original Records (2)

HHS interprets "original provider records" to include:

(1) Original records (e.g., reports or documents) that are required of a provider to meet any Federal, state, or local public health or health oversight requirement regardless of whether such records are maintained inside or outside of the provider's PSES; and

(2) copies of records residing within the provider's PSES that were prepared to satisfy a Federal, state, or local public health or health oversight record maintenance requirement, if while the provider is obligated to maintain such information, the information is only maintained by the provider within the PSES (e.g., if the records or documents that were being maintained outside the PSES to fulfill the external obligation were lost or destroyed)."

The Guidance: External Obligations

2. Original Records (3)

Understanding Paragraphs (1) and (2) of the Previous Slide:

- Paragraph (1) includes, but is not limited to, original records that are subject to an external reporting requirement but have not yet been reported.
- Paragraph (2) applies to information that is subject to a record maintenance requirement when the time that the information must be maintained has not expired (e.g., regulator requirement; time frame to maintain medical record information, risk management, etc.).
- If a provider has reported the information as required or the period for maintaining the information has expired, copies of original records in a provider's PSES (created for reporting to the PSO) will remain PSWP.

The Guidance: External Obligations

2. Original Records (4)

The Guidance Provides 4 Hypothetical Examples:

1. The provider only maintains the forms outside of the PSES: The forms are not PSWP.
2. The forms outside the PSES are not PSWP; the ones inside are as long as the ones outside are available: The **original** forms are not PSWP.
3. The provider only maintains the original forms in the PSES: The forms are original provider records and not PSWP.
4. The provider maintains the forms outside of the PSES and within the PSES extracts information from the forms to conduct further analysis: The forms are not PSWP.

The Guidance: External Obligations

3. Copies of PSWP

Under the Patient Safety Rule, the term “copy” is used in two ways:

1. As used in the previous section, copies refers to information that begins as non-PSWP (*i.e.,* original patient or provider records and/or information that was collected, maintained, developed, or exists separately from the PSES). While such information is ineligible to itself become PSWP, a copy of such ineligible information that is assembled or developed solely for reporting to the PSO can become PSWP through the reporting pathway.

   However, protection of the copy reported to the PSO does not provide PSWP protections to the ineligible information on which the copy is based. As discussed in the previous section on original records, a provider must take care to ensure that if the ineligible information is subject to any disclosure or record/system maintenance requirements, a provider must ensure that a non-PSWP version of the ineligible information is available to meet the provider’s obligations.

2. The term “copy” also appears at the end of the introductory language of the definition of PSWP. As the Guidance notes, "Consistent with the Patient Safety Rule’s definition of PSWP, copies of information initially prepared as PSWP within the PSES are PSWP."

The Guidance: External Obligations

4. Separate Systems (1)

Role of a Provider PSES in the Reporting Pathway

- PSES definition: it is the "collection, management and analysis of information ***for reporting to or from a PSO***."
- A PSES "***is separate, distinct, and resides alongside but does not replace other information collection activities…***" 73 FR 70742, Nov. 21, 2008; see also 73 FR 8124, Oct. 5, 2007.
- "....a provider should ***only place information in its PSES if it intends to report that information to the PSO***" 73 FR 70741–42, Nov. 21, 2008.

The Guidance: External Obligations

4. Separate Systems (2)

The Guidance clarifies that:

- The ability of a provider to remove information from its PSES (the drop-out provision) is intended to be used as a "safety valve" and intended to be used on a "case-by-case" basis when a provider discovers after information enters its PSES that the information is needed for another purpose.
- A provider should not enter information into its PSES that it recognizes is needed to meet its other obligations; moreover, information enters into a provider's PSES "remains PSWP (so long as it meets the requirements for being PSWP, including that it is not an original patient or provider record)…"
- The Department's prior statement that "a provider should maintain at least two systems or spaces: A PSES for PSWP and a separate place where it maintains records for external obligations.

The Guidance: External Obligations

5. Shared Responsibility (1)

- It is the provider's ultimate responsibility to understand what information is required to meet all of its external obligations.
- If a provider is uncertain what information is required of it to fulfill an external obligation, the provider should reach out to the external entity to clarify the requirement.
- HHS encourages communication between providers, PSOs, and regulators to ensure that the regulators can obtain the information they need without requesting that providers impermissibly disclose PSWP.
- HHS reminds regulatory agencies and other entities requesting information of providers or PSOs that, subject to the limited exceptions set forth in the Patient Safety Act and Patient Safety Rule, PSWP is privileged and confidential, and it may not be used to satisfy external obligations.

The Guidance: External Obligations

5. Shared Responsibility (2)

- When regulatory requirements are clear and discrete, it is relatively easy for providers to understand what information is mandated, determine what additional information they want to prepare for reporting to a PSO, and to separate the two categories of information.
- However, HHS is aware that some requirements are more ambiguous or broad, thus creating uncertainty about the information required to satisfy them…it is imperative that the regulators work with providers so that the regulators obtain the information they need, and that providers sufficiently understand what is required …so that they can satisfy their obligations and voluntarily report additional information to a PSO.
- Where a variety of information could potentially satisfy an external obligation, and where a provider reports similar information to the PSO, the provider may find it helpful to document which information collection activities it does to fulfill its external requirements and which other activities it does in the PSES, to help ensure confidentiality and privilege of the PSWP.

The Guidance: External Obligations

6. Later Developing Requirements (1)

- Situations could arise where a provider has collected information for reporting to a PSO and where the records at issue were not required by any external obligation at the time they were created, but where a regulator later seeks the same information.
- The information at issue would be PSWP and would be privileged and confidential, but the provider may still have several options to satisfy its obligation.
- If the information is being protected through the reporting pathway and is eligible for the drop-out provision since the provider has not yet reported the information to a PSO), then the provider may follow the drop out provision.
- If the provider has reported the information to a PSO or the information is otherwise not subject to the drop out provision (e.g., an RCA conducted in a PSES) , the Patient Safety Act and Patient Safety Rule provide several options that the provider may want to consider.

The Guidance: External Obligations

6. Later Developing Requirements (2)

1. *Did the provider mistakenly enter information that is not PSWP into its PSES?*

First question to ask: Does the information meet the definition of PSWP? If it does not meet the definition of PSWP :

- The provider can remove the information from its PSES.
- If the only copy of the information is in the PSO's PSES (i.e., the provider did not retain a copy outside of or in its PSES), then the Patient Safety Act places no limitations on the PSO from releasing it back to the provider.

The Guidance: External Obligations

6. Later Developing Requirements (3)

2. *If the information being sought by a regulator is PSWP, is there a disclosure exception that may be used to permissibly disclose the PSWP? For example:*
   - *Authorization by each identified provider? 42 CFR 3.206(b)(3)*
   - *Is the information subject to the FDA disclosure permission? 42 CFR 3.206(b)(7)*
   - *Is the information being voluntarily disclosed to an accrediting body, pursuant to 42 CFR 3.206(b)(8)?*

While these disclosure permissions are available in the limited circumstances described in the Patient Safety Rule, relying upon a disclosure permission should not be a provider's primary method to meet an external obligation.

The Guidance: External Obligations

6. Later Developing Requirements (4)

3. *Can the provider recreate the information or conduct an identical analysis from non-PSWP outside of the PSES?*

- If a provider… previously assembled such information within its PSES and reported it to a PSO, this does not prevent a provider from creating the requested information using non-PSWP. As indicated in the NPRM, ‘‘[t]hose who participated in the collection, development, analysis, or review of the missing information or have knowledge of its contents can fully disclose what they know . . .’’
- Similarly, although an analysis originally conducted in the PSES cannot become non-PSWP under the drop out provision, if a provider is informed that a certain analysis is needed to meet an external obligation, the Patient Safety Act indicates that a provider could conduct a new analysis with non-PSWP to satisfy this requirement, ‘‘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 PSES.

Resources

- Visit the PSO Website (www.pso.ahrq.gov)
- View the Video and flow diagram entitled, "Working With A PSO – One Approach"
- Contact AHRQ with questions pso@ahrq.hhs.gov