AQIPS | ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY

PSOs and Healthcare Providers Advancing Patient Safety

17-CV-B

SUBMITTED ELECTRONICALLY
January 24, 2017

Committee on Rules of Practice and Procedure
Administrative Office of the United States Courts
One Columbus Circle, NE
Washington, DC 20544

Re: Proposed Amendment to Federal Civil Procedure Rule 45

To Whom It May Concern:

The Alliance for Quality Improvement and Patient Safety ("AQIPS") respectfully submits the following proposed new paragraph as an amendment to Federal Civil Procedure Rule 45 – Subpoena:

> (h) Patient Safety Organization - Limitation on Actions. A Patient Safety Organization (PSO) cannot be compelled to disclose information collected or developed pursuant to the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C.§299b-21 et seq., whether or not such information is patient safety work product, unless the information is identified, is not patient safety work product, and is not reasonably available from any other source.

The Patient Safety and Quality Improvement Act of 2005 (42 USC §299b-21 et seq.; the "Patient Safety Act") substantially alters federal subpoena practice in actions against PSOs by prohibiting a PSO from being compelled to disclose patient safety work product (42 U.S.C. §299b-22(d)(4)(A)(i)). This provision is unique by providing immunity to a PSO for patient safety work product in its possession while placing on the person issuing the subpoena the burden of proving that the identified information is not patient safety work product and cannot be reasonably obtained from another source. For this and other reasons explained in the attached memorandum, this amendment is necessary to secure the public policy and the public health basis that Congress intended to allow PSOs to collect health care quality data, analyze such data and provide feedback for the benefit of patients.

AQIPS is a national professional organization for PSO's and their healthcare provider members whose mission is to foster the ability of healthcare providers to improve patient safety, the quality of patient care and patient outcomes through the privilege and confidentiality protections of the Patient Safety Act. AQIPS appreciates the opportunity to submit this petition. Should you have any questions or require additional information, please contact me at pbinzer@allianceforqualityimprovement.org. Thank you for your consideration.

Sincerely yours,

Margaret C. Binzer, J.D.
Executive Director and General Counsel AQIPS
Attachment

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PSOs and Healthcare Providers Advancing Patient Safety

MEMORANDUM

TO: United States Courts Committee on Rules of Practice and Procedure

FROM: Alliance for Quality Improvement and Patient Safety (AQIPS)

RE: Federal Civil Rule Amendment Proposal

Date: January 24, 2017

Introduction

The Alliance for Quality Improvement and Patient Safety (AQIPS) requests approval from the Committee to submit the following proposed addition to Federal Civil Procedure Rule 45 to the Federal Rules Advisory Committee for consideration, and if accepted by the Advisory Committee, for publication and comment.

Rule Amendment Proposal

Issue: The Patient Safety and Quality Improvement Act of 2005[1] (the "Patient Safety Act") substantially alters subpoena practice by setting forth a limitation on actions against a Patient Safety Organization (PSO)[2] for patient safety work product[3] and specifying three elements that a person issuing the subpoena must satisfy to compel from a PSO information that is not patient safety work product. The Patient Safety Act provides:

> Limitation on Actions; a Patient Safety Organization (PSO) cannot be compelled to disclose information collected or developed under [the Patient Safety Act], whether or not such information is patient safety work product, unless the information is identified, is not patient safety work product, and is not reasonably available from any other source.[4]

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[1] 42 USC §299b-1 et seq.

[2] A Patient Safety Organization (PSO) means a private or public entity or component thereof that is listed as a PSO by the Secretary in accordance with Subpart B. 42 U.S.C. §299b-24(d); 42 C.F.R 3.20. see www.pso.ahrq.org for listed PSOs.

[3] 42 U.S.C. §299b-21(7); 42 C.F.R. 3.20.

[4] 42 U.S.C. §299b-22(d)(4)(A)(i)).

This statutory provision is *sui generis* by providing immunity to a PSO for patient safety work product in its possession as a protection in addition to the privilege provided for patient safety work product to ensure that PSOs are not subject to litigation and to ensure the protected information is kept out of litigation. The Patient Safety Act is the cornerstone of the Federal effort to reduce preventable injuries and death from our health care system. Congress believed the work of a PSO to be so vital to the public health that it established special rules to limit the information that a PSO can be compelled to provide. The Patient Safety Act places the burden upon the person issuing the subpoena to prove the three elements required to demonstrate that the information is not patient safety work product rather than upon the PSO to move for a protective order. Because of the uniqueness of the statutory scheme and the importance of the public policy at stake, the amendment to the rules is manifest to alert practitioners that they should not seek issuance of the subpoena unless they can provide to the court sufficient evidence to demonstrate each element of the statutory exception. The proposed change to Fed.R.CivP. 45, which modernizes the rule, is necessary in order to incorporate other federal law governing the issuance of subpoenas, namely 42 U.S.C. § 299b-22(d)(4)(A).

Proposed Amendment and Rationale: A new paragraph (h) is proposed for consideration by the Federal Rules Advisory Committee as an amendment to Federal Rule Civil Procedure 45, Supoena:

> (h) Patient Safety Organization; Limitation on Actions; a Patient Safety Organization (PSO) cannot be compelled to disclose information collected or developed pursuant to the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §299b-21 et seq., whether or not such information is patient safety work product, unless the information is identified, is not patient safety work product, and is not reasonably available from any other source.

The Patient Safety Act authorized the creation of Patient Safety Organizations to improve patient safety, the quality of patient care and patient outcomes by reducing the incidence of events that adversely affect patients. Congress passed the Patient Safety and Quality Improvement Act (PSQIA) to create a 'culture of safety' by providing a privilege and confidentiality protection for quality information known as patient safety work product and permitting the sharing of patient safety work product to continuously improve the quality of patient care. The system was intended to "promote a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about health care errors to a 'culture of safety' that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors."[5] Congress designed the Patient Safety Act to foster a "learning environment" that would allow health care providers to assess their errors without fear that data and analysis will be subject to discovery in medical malpractice or enforcement actions.[6] The protected information is called "patient safety work product" and is defined as:

> (1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, record, memoranda, analysis (such as root cause analyses), or written or oral statements (or copies of any of this material)
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> (i) Which could improve patient safety, health care quality, or health care outcomes; and
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> (A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system; or
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> (B) Are developed by a PSO for the conduct of patient safety activities; or
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> (ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

[5] S. Rep. No. 108-196, at 2 (2003).
[6] HR Rep. 109-197 at 9 (2005).

(2) Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.[7]

To ensure that PSWP that is collected and analyzed for the benefit of patients is not used against providers in lawsuits, Congress granted privilege[8] and statutory confidentiality protections[9] for patient safety work product and limited actions against a PSO.[10] The statutory limitation prohibits actions against a PSO to compel patient safety work product. The statute provides an exception for actions against a PSO for information that is a) identified, b) is not patient safety work product, and c) is not reasonably available from any other source. The requirement that the information that is not patient safety work product be "identified" is to prevent fishing expeditions by plaintiff's lawyers looking to collect information that could identify the analysis of the PSO, which is by definition patient safety work product. The second element of the exception clarifies that only information that is not patient safety work product may be compelled from a PSO and therefore, the person issuing the subpoena bears the burden to demonstrate that the information that they are attempting to obtain from the PSO is not patient safety work product within the meaning of the law. Therefore, only documents, under subpart (b) of the definition of patient safety work product, such as original documents that are not patient safety work product can be compelled if the third element is also satisfied; that is the information cannot be reasonably obtained from another source. Many original documents identified in the Patient Safety Act are required to be maintained by healthcare providers under state or federal

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[7] 42 U.S.C. §299b-21(7); 42 C.F.R. §3.20. A patient safety evaluation system means the collections, management, or analysis of information for reporting to and by a PSO. 42 USC §299b-21(6); 42 C.F.R. §3.20.

[8] 42 USC §299b-22(a)

[9] 42 U.S.C. §299b-22(b).

[10] 42 U.S.C. §299b-22(d)(4)(A)(i).

statute or regulation and thus, the PSQIA requires the person issuing the subpoena under the third element of the exception to obtain the information from a provider or other sources rather than the PSO.

Importantly, Congress did not intend that this limitation on action prohibit plaintiffs from redressing harm:

> "The committee notes that protecting data in a reporting system as recommended in this chapter does not mean that the plaintiff in a lawsuit could not try to obtain such information through other avenues if it is important in securing redress for harm; it just means that the plaintiff would not be assisted by the presence of a reporting system designed specifically for other purposes beneficial to society."[11]

The statute provides that nothing in this part shall be construed to limit information that is not patient safety work product from being discovered or admitted in a criminal, civil or administrative proceeding.[12] By its plain language, the Patient Safety Act prohibits an action against a PSO for patient safety work product but provides an exception to access information that is not patient safety work product provided that sufficient evidence is provided to the Court to justify each element of the statutory exception.

This proposed amendment to rule 45 is necessary to secure the important public policy and public health basis by codifying the procedural requirements provided in the Patient Safety Act. The use of PSOs is becoming commonplace as health care providers are required or permitted to report to PSOs in several Federal laws.[13] Moreover, the amendment comports with the goals of the Rules of Civil Procedure as set forth in Rule 1, that the rules be construed and

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[11] S.Rep. No. 108-196 at 5, 7.

[12] 42 C.F.R. §3.20 *Patient safety work product* (2)(iii)(A).

[13] See section 1311 of the Affordable Care Act (42 U.S.C. § 18001 et seq. (2010)) and Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models, 81 Federal Register 77008 (November 4, 2016).

administered to secure the just, speedy, and inexpensive determination of every action and proceeding. Without the amendment plaintiff and defense lawyers may not be aware of their procedural responsibilities under Federal law potentially leading to unnecessary litigation and the erosion of the immunity Congress specifically granted to patient safety work product possessed by a PSO.

CONCLUSION

AQIPS urges the Committee to submit the following proposed addition to Federal Rule Civil Procedure 45 to the Federal Rules Advisory Committee for consideration, and if accepted by the Advisory Committee, for publication and comment. The addition of the new paragraph to Rule 45 would provide a needed federal civil procedure rule for the limitation on action contained in the Patient Safety Act.