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Illinois Department of Financial and Professional Regulation (IDFPR) vs Walgreen Co.

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Disclaimer

The opinions expressed in this presentation are those of the presenter and do not reflect the official position of the Department of Health and Human Services (HHS), the Agency for Healthcare Research and Quality, or the Office for Civil Rights. The statements do not constitute legal advice from either the HHS Office of the General Counsel or the presenter.



The Patient Safety Research Foundation – Walgreen Co.'s PSO

- Incorporated as an Illinois non-profit in 2006
- Mission is to improve quality throughout the company
- Listed/certified as a component PSO of Walgreen Co. on January 14, 2009
- Recertified on 1/13/12 through 1/12/15
- Subject to audit/federal regulations
- Staff consists of Walgreen Co. employees that serve as contracted workforce of the PSO



PSRF and Walgreen Co. PSES (1)

- Prior to the PSQIA, Walgreens had a comprehensive quality improvement program referred to as "CQI" .
- The purpose of the CQI program was to raise awareness about quality-related events and provide the means to determine how to prevent such events in the future.
- Participation in the CQI program was mandatory for all pharmacy staff.
- The CQI program was designed to:
 - improve patient safety and the quality of health care delivery by promoting accuracy in the dispensing of prescriptions
 - enhance the development and training of pharmacy personnel
 - ensure consistency in providing pharmaceutical care services.



PSRF and Walgreen Co. PSES (2)

- The CQI Program was the blueprint for designing the Walgreen Co. PSES.
- Walgreen Co. providers utilize a proprietary reporting system known as the Strategic Tracking and Analytical Reporting System ("STARS") to track and report external quality events.
- An external quality event is defined as an improperly processed or filled prescription that is dispensed to the customer.
- Providers are required to complete a STARS report for all external events as soon as possible, and in no event no later than the end of their shift.
- Once the event is entered into the STARS system, a Supervisor is notified to review the report.
- The Supervisor reviews the report and ultimately submits the completed STARS report to The Patient Safety Research Foundation, Inc. ("PSRF").



PSRF and Walgreen Co. PSES (3)

- Walgreen Co. has contracted with the PSRF to serve as its component PSO pursuant to the PSQIA.
- PSRF analyzes the information contained within the STARS reports and makes recommendations to Walgreen Co. providers which are designed to improve the quality of the prescription dispensing process.
- Walgreen Co. considers the STARS reports to constitute privileged "patient safety work product" pursuant to the PSQIA.
- The STARS system is maintained electronically and all reporting through the system is considered strictly confidential.
- Walgreen Co. does not create, maintain, or otherwise have in its possession incident reports pertaining to medication errors other than STARS reports.
- There are no other incident reports pertaining to medication errors that exist separately from the STARS reporting system.



IDFPR v. Walgreen Co.

- On 7/1/10, the IDFPR issued subpoenas requesting “All incident reports of medication error involving” three Walgreen Co. providers for periods as long as six years and into the future.
- Walgreen Co. served timely objections.
- On 10/8/10, the IDFPR filed suit in Lake County, IL seeking enforcement of the subpoenas.
- Walgreen Co. filed a Motion to Dismiss supported by affidavits establishing:
 - Walgreen Co. and PSRF PSES
 - Use of STARS reporting database
 - Treatment of the STARS reports as PSWP



IDFPR v. Walgreen Co. - Trial Court Ruling

- On 4/7/11, the trial court issued an order dismissing the Department's petition with prejudice as to all issues.
- The Court found that:
 - Walgreen STARS reports are incident reports of medication errors as sought by the Department;
 - STARS reports are PSWP and are confidential, privileged and protected from discovery under the PSQIA;
 - The PSQIA preempts contrary state laws purporting to permit the Department to obtain such reports.



IDFPR v. Walgreen Co. – Appellate Opinion

- Walgreen Co. established that the only documents responsive to petitioner's subpoenas' narrow scope of "incident reports" were STARS reports.
 - The affidavits confirmed that the STARS reports were transmitted to a PSO.
 - Accordingly, Walgreen Co. established that its STARS reports were privileged PSWP pursuant to section 299b-21(7) of the PSQIA.
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IDFPR v. Walgreen Co. - Lessons Learned

- PSES – If you build it, they WILL come (after it).
- Document process, especially reporting.
- Limit your responses to the plain language of the subpoena or request – your opponent will not impose any such rational limit when interpreting your response.
- Opponents of the privilege will attempt:
 - To create questions of fact
 - Distort terms and requirements of PSQIA:
 - Maintained separately
 - Created for the purpose of
 - Reported to
 - Misconstrue proper uses of PSWP, waiver and disclosure issues



Questions

