



Meeting Pharmacy Compliance and Regulatory Challenges

Comprehensive Pharmacy Services drives compliance with an end-to-end process: complete assessment, strategy development and implementation.

THE CHALLENGE:

Achieving and sustaining compliance across the entire healthcare organization and lowering regulatory risk while improving operational efficiency and effectiveness are critical goals for hospital and health system pharmacies. When Dayton Children's Hospital reached out to Comprehensive Pharmacy Services (CPS) for support in assessing compliance and regulatory issues for controlled substances, sterile compounding (USP <797> and <800>), The Joint Commission standards and 340B, CPS responded with custom solutions from its Compliance and Regulatory Services and 340B teams.

SOLUTIONS & RESULTS:

Sterile Compounding (USP <797> and <800>)

SOLUTIONS: In January 2018, the Compliance and Regulatory Services team provided a full assessment of compounding safety practices from procurement to administration in Dayton Children's Hospital's four compounding locations that included review of:

- Facility design
- Workflow observations
- Equipment and engineering controls
- Environmental sampling
- Cleaning and disinfection
- Policy and procedures surrounding sterile compounding

Following the assessment, the Compliance and Regulatory Services team drafted a Compliance Report and developed a plan for process improvement designed to optimize safety, efficiency and effectiveness, and compliance. At the request of the organization, due to a plethora of ongoing projects on the current Director of Pharmacy's agenda, the Compliance and Regulatory Services team offered a custom approach to managing the execution of

the project plan remotely. Currently an ongoing project, the Compliance and Regulatory Services team is virtually managing implementation and execution of the line items in the plan, ensuring that timelines are met and freeing up the Director of Pharmacy for other responsibilities.

RESULTS: As of March 2018, the project plan is approaching 25 percent completion. In February 2018, the Board of Pharmacy surveyed one of the organization's four sterile compounding locations. Because some of the items identified in the project plan were being acted upon, the surveyor issued no further citations. At another location, guidance is currently being provided for a full remodel of the sterile compounding suite which includes working directly with the pharmacy team, architects, engineers and facility administration.

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**IDENTIFIED \$500,000
IN ADDITIONAL 340B OPPORTUNITIES**



CONTROLLED SUBSTANCE COMPLIANCE

SOLUTIONS: In August 2017, CPS' Compliance and Regulatory Services team performed a complete controlled substance assessment at the request of hospital leadership.

Utilizing the Controlled Substance Diversion Prevention Assessment tool in the Comprehensive Pharmacy Assessment Platform, the Compliance and Regulatory Services team identified opportunities across the healthcare organization for improvement in management of controlled substances processes and developed an action plan, timeline and tools to track and manage implementation of the overall strategy.

RESULTS: From August 2017 when the initial assessment was made until to February 2018, the Compliance and Regulatory Services team worked with the hospital and pharmacy leadership to identify 105 opportunities for process changes, including several best practices. While still an ongoing project, the team has implemented process to address 63 of these opportunities. Of the remaining 42 opportunities, all but 9 are currently in the process of being addressed.

340B

SOLUTIONS: In October 2017, CPS' 340B team performed an initial evaluation, looking at both compliance and business opportunities. After digging deep into the on-site processes, the 340B team identified a number of manual functions that had not been evaluated previously.

From the assessment, they put together a road map defining what needed to be done in what timeframe. The team ensured that the organization was hitting timelines for establishing policies and procedures as well as internal audit processes. The plan also identified ways to optimize 340B benefits and save significant dollars for the hospital.

RESULTS: CPS' 340B team was able to take a good 340B program to a great 340B program and identified \$500,000 in additional 340B opportunities. The hospital has engaged CPS with a 3-year Continuous Readiness program to help the organization maintain a state of continuous audit preparedness. The 340B team meets with the pharmacy leadership every quarter to update where they are and provide assistance as needed.



THE JOINT COMMISSION

SOLUTIONS: In February 2018, the Compliance and Regulatory Services team conducted a comprehensive assessment and follow-up with a gap analysis, and then drafted a strategy for meeting The Joint Commission Accreditation Medication Management standards.

RESULTS: The strategic plan has been delivered to the on-site pharmacy director, and the Compliance and Regulatory Services team is assisting with implementation of that plan.

SUMMARY

In each of the Compliance and Regulatory areas, CPS' Compliance and Regulatory Services and 340B teams:

- Assessed the current pharmacy situation
- Drafted a strategy with a customized approach designed to meet the specific needs of the hospital
- Worked alongside the Pharmacy Director to engage the pharmacy team and drive accountability and execution of the outlined strategy
- Utilized proven tools, including Gantt charts, to assign timelines and virtually manage implementation

The agility shown by CPS Compliance and Regulatory Services and 340B teams in designing strategies to meet the specific needs of Dayton Children's Hospital helped improve and maintain regulatory compliance and medication safety, mitigate risk and promote operational integrity in the current complex regulatory healthcare environment.

ABOUT DAYTON CHILDREN'S HOSPITAL

Located in Dayton, Ohio, Dayton Children's Hospital is the only pediatric hospital in the Dayton region. The hospital serves more than 300,000 patients each year including infants, children and teens, and provides services in more than 35 specialties. Dayton Children's Hospital recently received the 2018 Women's Choice Award® as Best Children's Hospital and the 7th Annual Dr. Frank Dono Best Practice Award in 2016 from the Ohio Patient Safety Institute.

ABOUT CPS

Founded nearly 50 years ago, and employing over 2,500 pharmacy professionals, Comprehensive Pharmacy Services is the nation's oldest and largest provider of pharmacy support services to more than 700 hospitals and healthcare facilities' pharmacies. CPS helps hospital pharmacists tackle complex problems such as hyperinflated drug costs, medication reconciliation, specialty pharmacy, operational effectiveness and staffing efficiencies, centralized distribution, ambulatory/retail pharmacies, compliance, 340B programs and much more, leading to increased quality, reduced admissions and lower costs.





EVERY SUPERHERO HAS A SUPPORT TEAM.

For Hospital Pharmacies, it's CPS.

The challenges never get easier. The tasks never cease. Every day operations require a lot of time, resources and expertise. When your pharmacy needs support, CPS is there. We provide industry-leading support services for areas including 340B, antimicrobial stewardship and sterile compounding. We arm you with the smartest analytics, high-performing tools, experts, and proven pharmacy best practices that will help you leap—as high as you want to go.



Ready for the next level? Send us a signal and we'll be there
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