

## Background

- The national opioid crisis requires a collaborative approach by health systems to prevent opioid misuse and overdose deaths while expanding access to treatments to address opioid addiction
- Buprenorphine ER injection is a Schedule III controlled substance indicated for adults with opioid addiction and is available through a restricted distribution program through the FDA REMS
- The buprenorphine ER injection ETASU REMS requirements are essential for patient safety, yet pose compliance challenges specific to health system controlled substance chain of custody and storage
- Specialty pharmacies must comply with regulatory and manufacturer contractual requirements while developing a comprehensive care model to support drug access and manage patients receiving this healthcare provider administered medication
- The objective is to describe the process of implementing a comprehensive program to safely manage patients receiving buprenorphine ER injection while satisfying the regulatory and manufacturer requirements

## Methods

- The pharmacy contacted the manufacturer in January 2018 to obtain a data contract to dispense buprenorphine ER injection
- FDA and DEA regulatory requirements were compiled and assessed for inclusion into a buprenorphine ER injection program
- Data elements required by the manufacturer, commercial payers and accreditation standards pertaining to specialty pharmacy, were reviewed and assessed for inclusion into a buprenorphine ER injection program
- These regulatory and contractual requirements were built into an internal patient management platform (PMP) utilized by pharmacy liaisons and specialty pharmacists to track patient outcomes and to perform patient outreach while implementing customized care plans and managing product chain of custody
- Training of pharmacy liaisons and specialty pharmacists on the regulatory requirements as well as clinical best practices for the safe use of buprenorphine ER injection occurred through the organization's learning platform. Training consisted of ETASU REMS requirements, Pharmacovigilance and Product Quality Complaint Reporting and Standard Operating Procedures (SOP)



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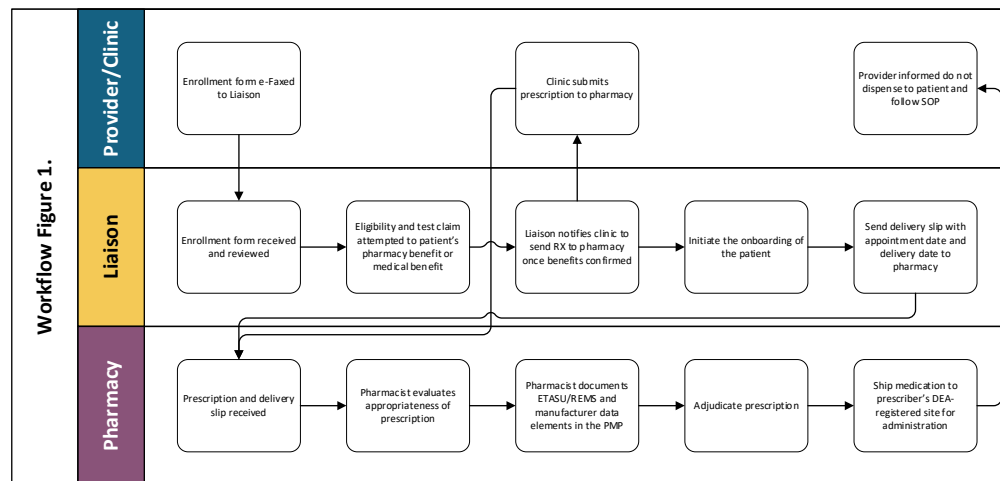


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## Results

- The timeline from securing a drug distribution & data contract to the first dispense was 21 months due to extensive requirements for program infrastructure. The PMP was customized to include the regulatory and manufacturer requirements in **Table 1** and workflow for the comprehensive care model was established per **Figure 1**
- Reported adverse events were managed by a pharmacist through a multidisciplinary approach resulting in customized patient care plans

Table 1. ETASU REMS Requirements		
Designated authorized representative	Healthcare setting and pharmacy enrollment	Staff training
Processes for dispensing to the healthcare provider	Notify healthcare provider not to dispense to patient	Change in authorized representative procedures
Distribution, selling and loaning restrictions	Records maintenance	Audit compliance
Manufacturer Requirements		
Shipping label requirements	Distribution, selling and loaning restrictions	Shipment and delivery tracking
Receipt of delivery confirmation	Processes for wrong or unsuccessful deliveries	Dispensing data file submissions
Reporting on license and registration changes	Reporting on investigations	Pharmacy benefit vs. medically billed
Adverse event reporting	Product quality complaint reporting	Reporting on non-compliance events
Policies and procedures for: a.) Verifying prescriber DATA-2000 waiver b.) Not dispensing to a patient c.) Verifying shipping location matches DEA-registered location for administration d.) Notifying prescriber not to dispense to a patient		



## Conclusions

- The provider-liaison-pharmacist care model achieved compliance with REMS, DEA, health-system and manufacturer requirements while expanding access to buprenorphine ER injection and enhancing patient care
- Integrated specialty pharmacies are ideally positioned to manage the complex requirements to safely dispense buprenorphine ER injection and provide coordinated care to address the opioid overdose epidemic

## References

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## Disclosures

The authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation