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March 16, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6502, "Opioid Policy Steering Committee: Prescribing Intervention - Exploring a Strategy for Implementation; Public Hearing; Request for Comments"

Via electronic submission: http://www.regulations.gov

Dear Dr. Gottlieb:

Thank you for the opportunity to comment on the work of the Opioid Policy Steering Committee and to contribute to the proceedings of the Steering Committee's public meeting held on January 30, 2018. Our comments specifically address the first of FDA's four areas of focus: Decreasing Exposure and Preventing New Addiction.

Surescripts is the nation's largest health information network, built to increase patient safety, lower costs and ensure quality care. Founded in 2001 by pharmacies and pharmacy benefit managers, we now connect over 99 percent of all retail pharmacies and most mail order pharmacies in the country, more than 250 EHRs and health technology vendors, representing more than 1,300,000 prescribers, and hundreds of health systems In 2017, we processed 13.7 billion healthcare transactions targeted at enhancing prescribing and informing care decisions, including 4.8 million e-prescriptions and nearly 7 million medication histories daily.

Our cross-market experience gives us a unique perspective on the role that health information technology (HIT) can play in providing actionable intelligence to help reduce opioid abuse while ensuring that patients receive quality care and clinically appropriate medications. Below we describe two of our services, Electronic Prescribing of Controlled Substances (EPCS), and Medication History, both of which can be effective tools in improving prescribing behavior and preventing opioid misuse and diversion. We make both EPCS and Medication History available through their EHRs to all ambulatory providers on our network, at no charge.

Electronic Prescribing of Controlled Substances (EPCS):

One of the most promising technology tools, EPCS can reduce illegal diversion, a significant driver fueling the opioid epidemic. Up to 9% of drugs diverted for abuse are tied to fraud and forgery of paper prescriptions. Broad adoption of EPCS would eliminate paper-based fraud. Equally important, it would create electronic records of controlled substance transactions, strengthening surveillance and improving accountability.

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EPCS is relatively new. While electronic prescribing has been in wide use for over seven years, use of the technology for controlled substances lagged because of regulatory restrictions, some of which were not resolved until 2014.

Unfortunately, nationwide EPCS use still remains relatively low. In 2017, only 19% of controlled substances were prescribed electronically, compared to 82% of non-controlled drugs. EPCS use requires both pharmacy and prescriber enablement to send and receive electronic prescriptions in a manner that meets regulatory requirements. While over 90% of pharmacies are now enabled to receive electronic prescriptions for controlled substances, only 30% of prescribers are enabled to send them. This lag in prescriber adoption is responsible for the relatively low national rate of EPCS use.

At the state level, there is a broad range of EPCS adoption and use. State-by-state data on EPCS adoption can be found in an interactive map on our website (http://surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-of-controlled-substances). The most successful states have both EPCS requirements and enforcement provisions in place. New York State is the top performer with 75% of prescribers and 94% of pharmacies enabled for use. New York's success is a consequence of the Internet System for Tracking Over-Prescribing (I-STOP) Act, which requires all prescriptions to be sent by electronic transmission. New York State Bureau of Narcotic Enforcement recently reported that the e-prescribing mandate is responsible for a 70% reduction in loss and theft of prescription forms and an 8% reduction in doctor shopping. Beyond New York, seven additional states have enacted EPCS-related laws. Four of the eight have already implemented their programs.

At the federal level there is no current EPCS requirement in place, but bipartisan bills have been introduced in the current Congress to require EPCS use for the Part D program. We applaud the actions of the bills' sponsors and federal policymakers like yourself who have publicly endorsed EPCS. We recommend that the Steering Committee support legislative and regulatory efforts to accelerate adoption and use of EPCS by prescribers. Surescripts regularly provides network data and technical assistance to state policymakers who are working on ways to incentivize EPCS. We would be pleased to provide similar assistance to the Steering Committee at your request.

Medication History:

Many participants in the Steering Committee hearing addressed issues related to Prescription Drug Monitoring Programs (PDMPs). Testimony on the current state-based PDMP structure and effectiveness was mixed. While some witnesses were strong advocates for the current system, others raised a number of concerns, arguing that some state systems are difficult to access, require providers to exit their EHR workflow, are unable to access patient drug history outside the state, and have difficulty with patient identification/matching across borders.

As the Steering Committee considers the current PDMP program and related efforts to deliver timely information to prescribers regarding a patient's history of controlled substance use, we want you to be aware of Surescripts Medication History service which is widely adopted by nearly all EHRs and can supplement PDMP data for prescribers at point of care.

Surescripts delivers nearly seven million HIPAA-compliant medication histories securely across our network every day. Our data covers 85% of U.S. patients nationwide, and offers providers access to their patients' dispensed medication history, including controlled substances, over the previous 12 months. Our data is refreshed daily and sourced from claims data from our commercial, Medicare and Medicaid PBM partners, and dispensed data from our community, retail and independent pharmacy partners. We deliver our data through providers' EHR systems, which configure it and create user interfaces for seamless use by the provider without having to leave their workflow. We have attached a description of the data elements included in our medication history as well as illustrations of how EHRs can display data to providers.

There are significant differences between PDMP reports and Medication History: (1) Medication History is not limited to controlled substances; (2) Medication History is delivered through the provider's EHR within the workflow, rather than a separate stand-alone PDMP service; (3) Medication history is sourced nationally rather than by state, so providers see the same patient history data, regardless of location or prescribing physician; (4) Surescripts uses a master patient index built upon the backbone of our network that allows us to match nearly 250 million patients with their records; and (5) Surescripts is fully interoperable, with all network participants using the same standards and held to the same degree of network quality.

Although Medication History addresses some of the concerns about PDMPs raised during the hearing, we are not suggesting that our service is a substitute for the PDMP system. We do not have universal state-level coverage as the PDMP program does, nor is our service accessible to law enforcement and the array of organizations that PDMPs serve at the state level. Rather, we wanted to make the Steering Committee aware of our service because we believe it can be a powerful tool, and an important supplementary source of information for providers who treat patients at risk of opioid-related illness.

We would be pleased to provide any additional information the Committee might find useful and we thank you for the opportunity to participate in this important work.

Best regards,

Mary Ann Chaffee
Vice President, Policy & Federal Affairs

Attachments

STRUCTURED DATA ELEMENTS ARE AVAILABLE FOR EACH MEDICATION

Medication History Data Elements

- **Patient Data**: Name, DOB, Gender, Address, Phone, etc…
- **Medication Data**: Name, quantity dispensed, days supply, date filled, date picked-up, refills, SIG, etc…
- **Prescriber Information**: Name, DEA, NPI, Address, Phone Number, etc…
- **Pharmacy Information**: Name, Address, Phone Number, etc…

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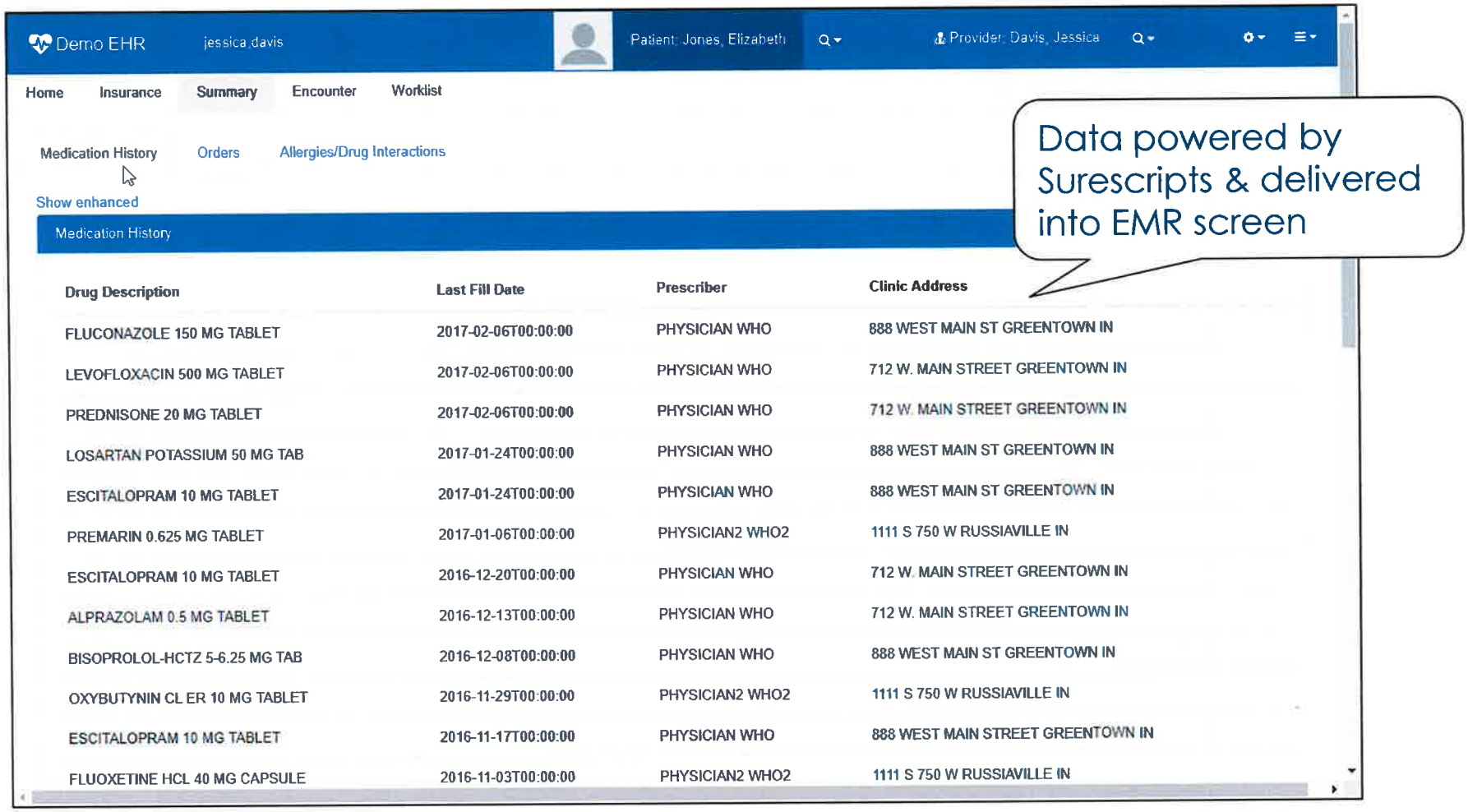
MEDICATION HISTORY DATA IS OFTEN SORTABLE. USERS CAN OFTEN CLICK ON ENTRIES TO SEE ADDITIONAL DETAILS.*



Drug Description	Last Fill Date	Prescriber	Clinic Address
FLUCONAZOLE 150 MG TABLET	2017-02-06T00:00:00	PHYSICIAN WHO	888 WEST MAIN ST GREENTOWN IN
LEVOFLOXACIN 500 MG TABLET	2017-02-06T00:00:00	PHYSICIAN WHO	712 W. MAIN STREET GREENTOWN IN
PREDNISONE 20 MG TABLET	2017-02-06T00:00:00	PHYSICIAN WHO	712 W. MAIN STREET GREENTOWN IN
LOSARTAN POTASSIUM 50 MG TAB	2017-01-24T00:00:00	PHYSICIAN WHO	888 WEST MAIN ST GREENTOWN IN
ESCITALOPRAM 10 MG TABLET	2017-01-24T00:00:00	PHYSICIAN WHO	888 WEST MAIN ST GREENTOWN IN
PREMARIN 0.625 MG TABLET	2017-01-06T00:00:00	PHYSICIAN2 WHO2	1111 S 750 W RUSSIAVILLE IN
ESCITALOPRAM 10 MG TABLET	2016-12-20T00:00:00	PHYSICIAN WHO	712 W. MAIN STREET GREENTOWN IN
ALPRAZOLAM 0.5 MG TABLET	2016-12-13T00:00:00	PHYSICIAN WHO	712 W. MAIN STREET GREENTOWN IN
BISOPROLOL-HCTZ 5-6.25 MG TAB	2016-12-08T00:00:00	PHYSICIAN WHO	888 WEST MAIN ST GREENTOWN IN
OXYBUTYNIN CL ER 10 MG TABLET	2016-11-29T00:00:00	PHYSICIAN2 WHO2	1111 S 750 W RUSSIAVILLE IN
ESCITALOPRAM 10 MG TABLET	2016-11-17T00:00:00	PHYSICIAN WHO	888 WEST MAIN STREET GREENTOWN IN
FLUOXETINE HCL 40 MG CAPSULE	2016-11-03T00:00:00	PHYSICIAN2 WHO2	1111 S 750 W RUSSIAVILLE IN

**EHR implementations and user interfaces vary. Image above for demonstration purposes only. Not real patient data.*

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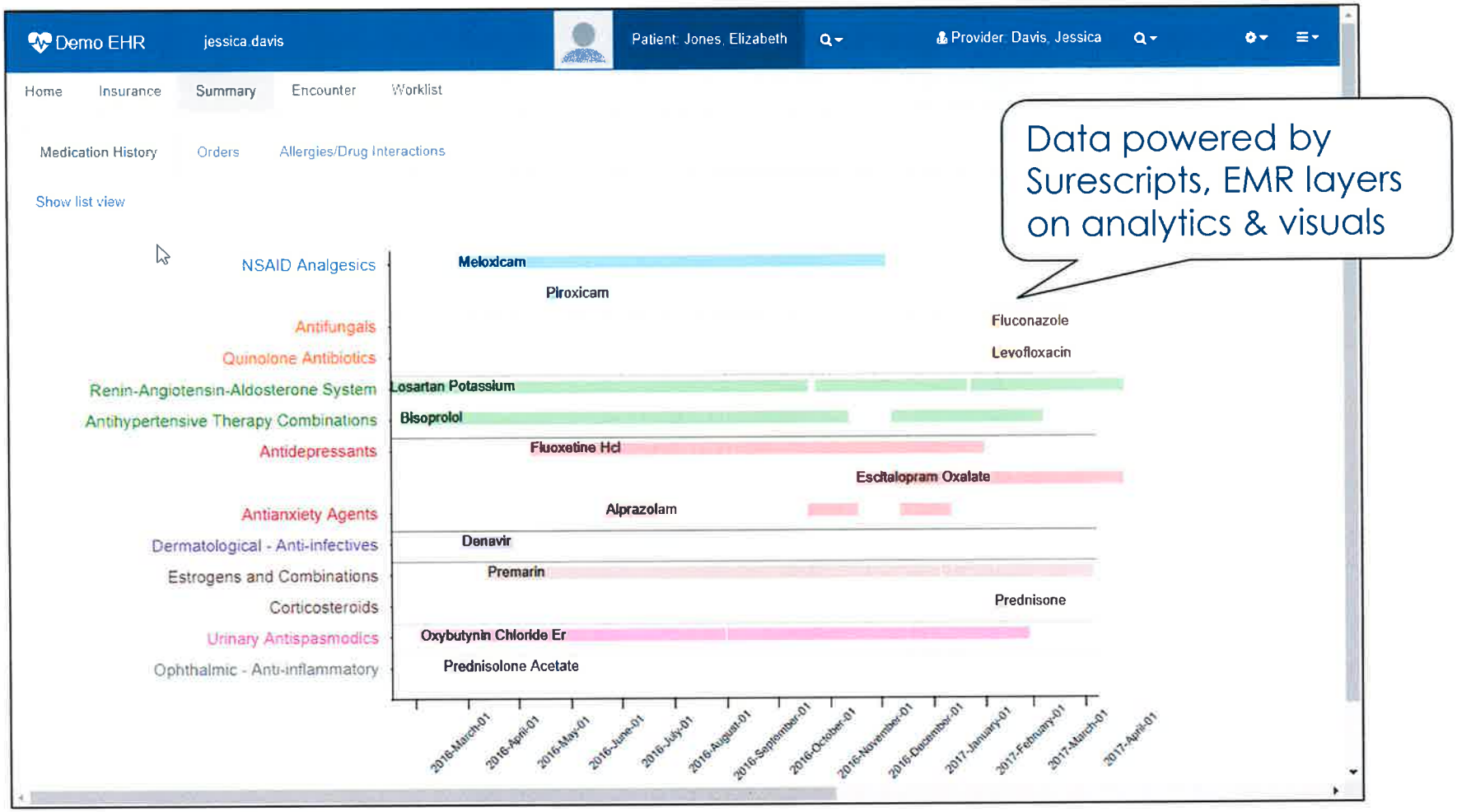
MEDICATION HISTORY DATA CAN ALSO BE VISUALIZED TO MORE EASILY SHOW OVERLAPS AND GAPS IN THERAPIES.*



*EHR implementations and user interfaces vary. Image above for demonstration purposes only. Not real patient data.

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