

## Pharmacogenetics: Pharmacy Evolution Rolls On

### THE PRACTICE OF RETAIL PHARMACY

continues to rapidly evolve, with no end in sight. In January 2020, common pharmacy concerns surrounded periodic drug shortages, Amazon's entry into the pharmacy space, declining reimbursement rates, and DIR (direct and indirect remuneration) fees. Within 12 months, pharmacies would be catapulted into the role of one of the nation's central vaccine providers in response to the COVID-19 pandemic. Pharmacies quickly operationalized the administration of multiple vaccinations and boosters into their dispensing and claims adjudication software. This year's federal Test to Treat COVID initiative challenged pharmacies to absorb yet another workflow change. Emerging from the shadow of COVID, however, other components of pharmacy practice are gathering momentum for disruption.

Pharmacogenetics and the need to capture standardized patient pharmacogenetic data within pharmacy systems are rapidly growing. Pharmacogenetics, sometimes called pharmacogenomics, is the study of the genetic factors that affect drug metabolism, drug transport, or drug receptors in individual people. Genetic variations cause individuals to respond differently to medications and may cause patients to be more or less sensitive to certain drugs, versus their peers. This results in the increased likelihood that a given drug will be ineffective or produce an adverse reaction. The FDA provides an alphabetical list of drugs with affected genes and gene subgroups, and a description of the gene-drug interaction.

### TESTING PRODUCTS

Pharmacogenetic testing products have been available in retail pharmacies since 2017; however, the integration of



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pharmacogenetic data into pharmacy systems, including standardized communications with payers or prescribers, has not been widely established in pharmacy operations. As health plans and PBMs integrate pharmacogenetic data into their formulary models, pharmacies will be required to receive, store, and integrate a patient's genetic profile. It is expected that this genomic data will be required as part of the prior authorization process and may be needed to determine formulary alternatives, which could be determined by the presence or absence of specific genetic information. The pharmacist can be notified to conduct a specific pharmacogenetic intervention or pharmacogenetic-required test. Pharmacies can offer pharmacogenetic (PGx) testing that can be completed at home or in the pharmacy.

Because the functionality to specifically capture pharmacogenetic data does not yet exist, pharmacies are using existing practice management system tools, such as the allergy tables, disease/problem lists, or pharmacy notes, to store a patient's genetic data. Doing this requires the pharmacist to manually monitor for interactions, determine appropriateness of therapy, and access additional references for detailed clinical pharmacogenetic information. The interoperability of pharmacogenetic data depends on pharmacy and payer systems' ability to share common data structures to digitize this communication. Options for prescriber and pharmacy systems include using internal technology services to design and implement pharmacogenetic data into an existing system or purchasing a software package to layer over or within an existing system. In the EHR (electronic health record) market, Genelex is an example of a laboratory corporation that has partnered with YouScript to provide a layered software package to integrate a patient's PGx results into existing EHRs. This software also provides

clinical decision support for the prescriber, and that support is specific to the genetic test.

Beyond pharmacies and prescribers, PBMs (pharmacy benefit managers) will also need access to pharmacogenetic data. For example, the NCPDP Foundation recently awarded a grant to Xact Laboratories, a biotechnology company focused on providing molecular diagnostic tests and results integration. The grant will be used to help integrate pharmacogenetic data into existing PBM systems. The Xact Vertical Integration System (XVIS) was developed for:

*“integrating laboratory test results data, particularly genetic-based pharmacological efficacy data, into existing electronic systems like electronic health records, healthcare information exchanges, payor systems, self-insured employer groups, and pharmacy benefits manager systems.”*

Xact would model incorporation of PGx data into PBM systems and/or modules, allowing direct communication between the pharmacy and payer. As described by NCPDP:

*“The Xact system would allow clinicians to make clinical decisions utilizing genomic data to better aid in their prescribing and drug choice but in line with the current processes in place today. Instead of incorporating an entirely new system to include this new genomic information, Xact Laboratories XVIS would incorporate themselves into the current systems already in use.”*

Similarly, pharmacy systems will require enhancements to accommodate patient genetic data and make this data accessible to the pharmacy’s clinical decision support tools. In such a system, an alert would trigger if a drug were prescribed that was contraindicated for patients with this specific gene. These alert functions are contingent upon the genetic profile being accessible to the clinical decision support software. Through a SCRIPT RxChange message, prescribers could be notified of more appropriate medications based on the PGx test outcomes. Pharmacists could also use SCRIPT RxChange messaging to send notifications for products with PGx considerations, requesting a prescription for a different product that may be more appropriate for the patient. These transactions offer prescribers an opportunity to see available alternatives or to issue a prescription for the product recommended by the pharmacist.

Once limited primarily to oncology treatments, PGx testing is in a period of rapid growth across many disease states. Historically, only hospital pharmacists had access to a patient’s genetic profile, but the enormous growth of self-testing and self-reporting has begun to create a need for retail pharmacies to be privy to genetic test results. As the utilization of PGx

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testing in patient care expands, so do the opportunities for pharmacists to better manage patient care on a personalized basis. By using pharmacogenetic testing, pharmacists can work with providers to improve patient outcomes and work with PBMs, pharmacies, and health systems to better implement personalized care. **CT**

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