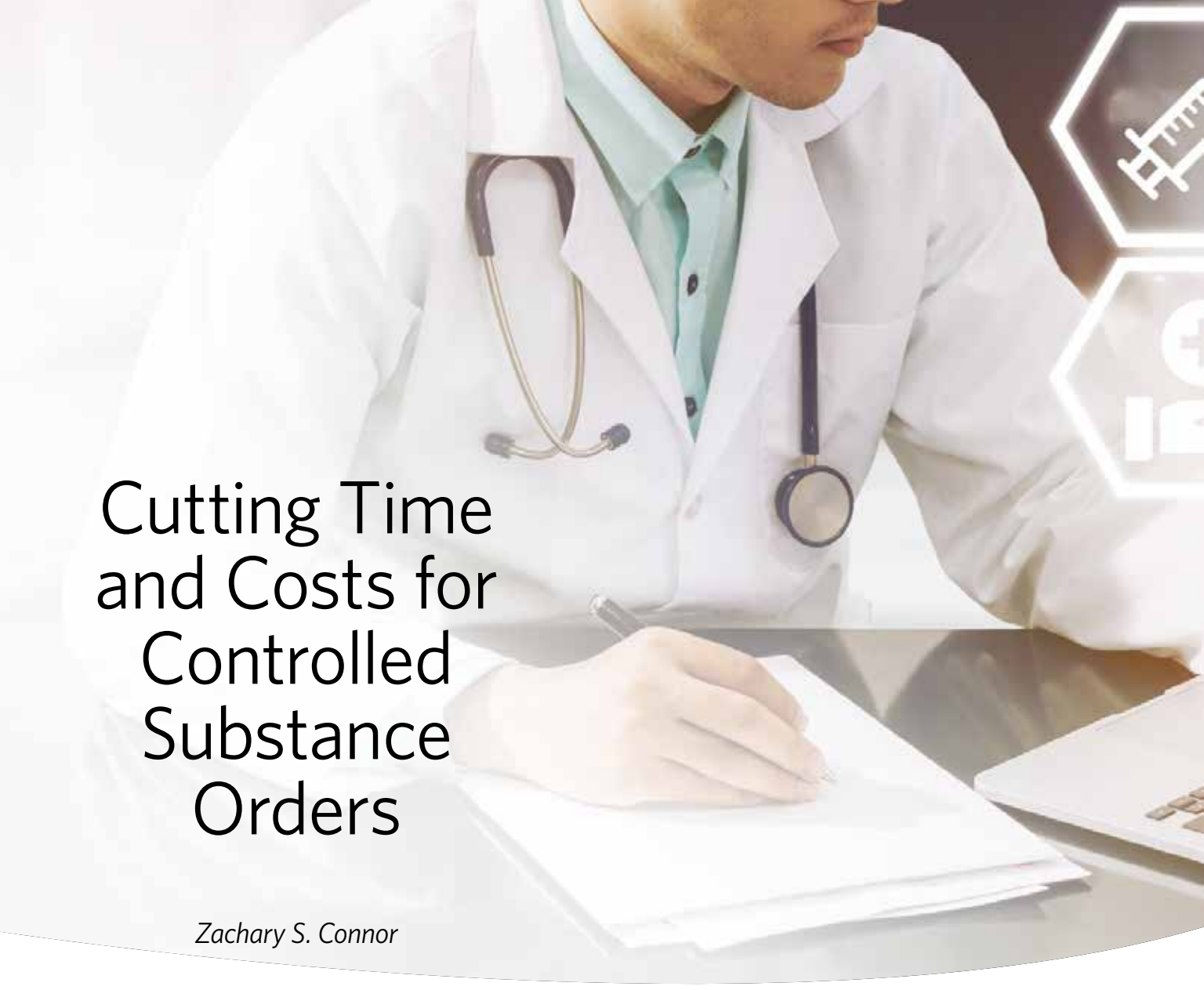

Cutting Time and Costs for Controlled Substance Orders

Zachary S. Connor

A WEB-BASED APPLICATION DEVELOPED BY THE JOINT MEDICAL LOGISTICS FUNCTIONAL DEVELopment Center (JMLFDC) dramatically reduced Schedule II controlled substance order processing and delivery time and expense by replacing paper-based processes with electronic orders.

"The goal of the Narcotics Order Review and Approval (NORA) program is to automate the ordering process to reduce the amount of time users were required to focus on ordering controlled substances," NORA program manager John Dittig explained.

Since its 2016 launch, NORA accelerated controlled substance order processing while cutting overall delivery times by 40 percent, he added. NORA also helped reduce Department of Defense (DoD) controlled substance acquisition costs by more than 27 percent over previous years' spending.

Part of the Defense Health Agency (DHA) Solution Delivery Division (SDD), JMLFDC provides DoD Medical Logistics (Med Log) application development and sustainment, maintains systems serving more than 24,000 users and processes more than 940,000 supply chain transactions daily with annual supply requisitions valued at $4.5 billion.

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Over the past 3 years, JMLFDC on-boarded more than 300 approved NORA users and executed more than 19,000 purchase orders, Dittig added. Approval and delivery times for continental U.S. (CONUS) customers dropped from between 5 and 7 days to just 1, while approval and submittal processing dropped from 4 days to less than a day for those outside the continental U.S. (OCONUS). Before NORA, Dittig said that the DoD spent $84.7 million on controlled substance orders over a 3-year period, whereas DoD spending fell to $61.6 million with NORA due to customers maintaining less on-hand inventory—a $23.1 million savings.

NORA users include Military Health System (MHS) pharmacists and the approved vendor, Dittig said. Applicants are screened by the Drug Enforcement Administration (DEA) and must meet federal government guidelines for ordering and distributing controlled substances.

Controlled Substance Regulations

Controlled substance distribution is regulated by Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, called the Controlled Substances Act. According to the DEA website, under the Act, Schedule II drugs are defined as those that have a high potential for abuse; are currently accepted for medical use in treatment in the United States or currently accepted for medical use with severe restrictions; and may lead to severe psychological or physical dependence if abused. Schedule II drugs include morphine, opium, codeine, hydrocodone and others.

Individuals who order, handle, store and distribute controlled substances, including DoD pharmacists, must be registered with the DEA, the site explains. Substance handlers also are required to maintain accurate inventories, records and security for the controlled substances.

Electronic Versus Paper Forms

Before electronic prescriptions or pharmacy applications may be used to transmit prescriptions, a third party must audit the application for compliance with the requirement of Title Code 21 of Federal Regulations part 1311, Dittig said. Title Code 21 rules govern creation, transmission and storage of electronic orders and prescriptions. Alternatively,

organizations whose certification processes have been approved by the DEA can verify that the applications meet the requirements.

NORA enables users to digitally sign Schedule II controlled substance orders and check their status online without the formerly requisite paper DEA Form 222, called the DEA 222. Dittig said NORA does this by enabling DEA registrants and their powers of attorney (POAs) to control the electronic submissions, which allows them to file electronic DEA 222s.

Dittig said electronic DEA 222 submissions are reviewed and cross referenced with the pharmaceutical vendor's inventory. When the available warehouse inventory is determined, additional orders for substitute pharmaceuticals can be placed for out-of-stock items. He said that the electronic orders take precedence over paper DEA 222 submissions. The vendor processes electronic submissions before any paper DEA 222 forms—and, if medication availability is limited, electronic orders are filled first.

"NORA put the DoD on a level playing field with our civilian counterparts who have been using the Controlled Substance Ordering System (CSOS), the DEA's version of NORA, for the past few years," noted Donald K. Pearson, a pharmacist at Langley Air Force Base in Virginia.

NORA's easy-to-use interface also provides a more user-friendly ordering system than paper forms and helps reduce potential administrative and dispersal errors, Dittig added. The automated process helps strengthen administrative controls for controlled substances management, resulting in reduced overall investments for sites that maintained large pharmaceutical inventories to accommodate longer delivery times.

"Productivity in our pharmacies has been increased through fewer out-of-stock medications," said Pearson, whose pharmacies annually place approximately 300 Schedule II controlled substance orders.

NORA Security Requirements

Initially, JMLFDC planned to use a commercial off-the-shelf (COTS) product to support NORA functions, Dittig said. COTS applications are designed to be used without modification and are relatively inexpensive because they often are mass-produced. However, he said that available COTS products did not meet stringent DoD cyber security requirements so the JMLFDC team opted for a government off-the-shelf (GOTS) product developed in-house.

"Using a GOTS product gave us the flexibility to design and build a system that met all our needs," Dittig explained. "It also allowed us to incorporate the DoD security safeguards early in the design process."

Dittig said that, after 6 months of progress developing NORA, JMLFDC was granted authority to operate the application in July 2015. Two months later, NORA received DEA third-party accreditation. Over the next 8 months, JMLFDC tested the system with vendors, the Defense Logistics Agency and the Defense Automatic Addressing System Center and completed enrolling DEA registrants before going live in August 2016.

Third-Party Verification

Before electronic prescriptions or pharmacy applications may be used to transmit prescriptions, a third party must audit the applications for compliance with federal regulations governing electronic order and prescription creation, transmission and storage. Or organizations meet the requirements if they have with DEA-approved certification processes and can verify that the applications meet the requirements.

To allow NORA to perform the requisite third party certification, Dittig said that the team decided to host the application in the JMLFDC Production Support Environment within the Fort Detrick, Maryland, Network Enterprise Center, separate from other JMLFDC applications, such as the Defense Medical Logistics Standard Support (DMLSS) Med Log application suite and the Theater Enterprise Wide Logistics System (TEWLS) portfolio.

CSOS Final Rule Document

Dittig said that, by being separate from DMLSS and TEWLS, NORA's third-party validation process complies with the DEA CSOS Final Rule Document, the electronic equivalent to the DEA official order form. The Final Rule Document is legally required for all distributions involving Schedule I and II controlled substances. The Document allows, but does not require, registrants to approve or disapprove an order for Schedule I and II substances electronically and maintain digital order records. The Final Rule Document reduces paperwork and transaction times for DEA registrants who handle, sell or buy controlled substances—but has no effect on patients' ability to receive prescriptions from practitioners, nor on practitioners' ability to have controlled substance prescriptions filled at a military pharmacy.

If embedded within DMLSS or TEWLS, NORA would have been subject to the DEA CSOS Final Rule Document. However, Dittig said that DMLSS and TEWLS users already have worldwide access to the NORA application to research order status since they meet public key infrastructure (PKI) access requirements. PKI is a set of roles, policies and procedures needed to create, manage,

distribute, use, store and revoke digital certificating and manage public-key encryption. Access to all DHA Med Log systems is PKI-controlled via common access cards (CACs).

NORA security standards are the only ones allowed for electronic transmission of Schedule II controlled substance orders between manufactures, distributors, pharmacies and other DEA ordering entities, Dittig said. "NORA is available to all DMLSS and TEWLS users worldwide. Currently there are more than 300 registrants or POAs who have signatory authority in NORA."

Approved users who have signatory authority must be registered with the DEA and authorized by the agency as either registrants or signatory approval POAs, he added. Once approved, registrants must participate in training for approving, signing or rejecting controlled substance orders. All NORA users must also register with the DEA to use the electronic DEA 222.

Users generate controlled substance orders in either DMLSS or TEWLS. The order is electronically transmitted to NORA via the Defense Automatic Addressing System (DAAS). After the electronic order form is generated, NORA will notify the registrant or POA of the pending order. From there, the registrant or POA logs into NORA and completes the approval or disapproval process. If the order is approved, NORA will complete the order process using the DEA certificate for the approver and send it to the DoD-approved pharmaceutical vendor via DAAS.

"Since its deployment, NORA has reduced costs, chain-of-custody problems and processing times along with cutting administrative and order fulfillment errors," noted SDD Chief Col. Francisco Dominicci. "It's a speedy, modern upgrade to a slow, antiquated process."

Dominicci said that NORA is one of several JMLFDC programs designed to create more streamlined, cost-efficient Med Log acquisition processes to help improve the patient experience for the MHS' 9.5 million-plus eligible beneficiaries.

"Another major program, called LogiCole, will eventually transition all Med Log applications, including NORA, into a single, Web-based suite on the cloud," he added. "The new suite will provide an enterprise view of all Med Log functions, including supply, equipment, medical maintenance and facility management. For acquisitions, LogiCole will use authoritative product and sourcing data to push users toward preferred, standardized items."

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