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June 14, 2018

The Honorable Gregg Harper
Chairman
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

The Honorable Diana DeGette
Ranking Member
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

Re: McKesson Corporation

Dear Chairman Harper and Representative DeGette:

On behalf of the McKesson Corporation,[1] please find below responses to the Committee's May 31, 2018 questions for the record related to the Committee's May 8, 2018 hearing regarding opioid distribution.

The Honorable Gregg Harper

1. **Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?**

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[1] McKesson U.S. Pharmaceutical is the business unit of McKesson Corporation that is relevant to the requests contained in the Committee's letter. Accordingly, the responses contained in this letter are based on information provided by McKesson U.S. Pharmaceutical. Throughout the letter, McKesson U.S. Pharmaceutical is referred to as "McKesson" or the "Company."

McKesson requests dispensing data from both prospective and existing pharmacy customers, and this information is an integral part of the company's due diligence efforts to mitigate controlled substance diversion. The company normally reviews a prospective customer's dispensing data as part of its due diligence before bringing on the new customer. The company requests and analyzes dispensing data from current customers when the customer requests to modify its controlled substance ordering thresholds. The company may also request dispensing data when it conducts a proactive or reactive review of an existing customer. This information allows McKesson to, for example, compare a customer's dispensing levels against its purchasing data, or to better understand a customer's business model.

2. **In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

As noted above, McKesson requires dispensing data of new customers as part of the onboarding process, and from current customers as part of various due diligence reviews. If a current customer refuses to provide dispensing data upon request, McKesson will generally not continue to supply the customer with controlled substances. If a prospective customer with a history of dispensing controlled substances refuses to provide dispensing data upon request, McKesson will generally not onboard the prospective customer until the data has been provided. McKesson's standard contract with independent and small- and medium-chain pharmacy customers reserves McKesson's right to terminate the relationship if the customer puts McKesson at risk of noncompliance with any law, regulation, or requirement involving controlled substances. McKesson can exercise that right when a customer refuses to provide dispensing data upon request. McKesson also may require those pharmacy customers to consent to sharing dispensing data in order to receive certain rebates based on purchasing.

3. **As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

McKesson has a tool that allows it to review a list of its current customers in the same city, state, zip code, or geographic radius as another of its customers. This tool also allows McKesson to compare available purchasing data for those customers. McKesson's onboarding process also asks prospective customers to define their service area. All of this information is available to McKesson when it conducts a review of a current or prospective customer. McKesson does not, however, assign its customers a set "service area." The retail pharmacy market is highly dynamic, with pharmacies opening, closing, and/or changing business models regularly. As a result, the "service region" of a pharmacy is an imprecise measurement that can expand and contract due to market factors. Additionally, a pharmacy's service area can be quite different than that of a neighboring pharmacy.

4. **Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?**

   This question is a duplicate of Rep. Harper's Question #1.

5. **In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

   This question is a duplicate of Rep. Harper's Question #2.

6. **As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

   This question is a duplicate of Rep. Harper's Question #3.

The Honorable Michael C. Burgess

1. **While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?**

This question appears to reference the Drug Enforcement Administration's ("DEA's") move to share a limited amount of its ARCOS database information via the Buyer Statistics Lookup tool on the DEA website. McKesson has been able to access that data. McKesson believes that this tool represents a start towards better data-sharing, but that including additional information would enhance the usefulness of the tool.

The current tool allows McKesson to search for a DEA registrant to see whether the registrant has purchased certain broad "base codes" of controlled substances and, if so, how many distributors sold those base codes to the registrant within a limited timeframe. The tool does not allow McKesson to see the quantity of product purchased in that base code, nor does it identify the specific product purchased or the strength of the product purchased. The information also covers only a recent six-month period and has about a one-month lag period.

The usefulness of the data is also limited by what is contained in the ARCOS database and when data is reported to the DEA. ARCOS does not, as stated in the question, include data on "controlled substance prescriptions." It includes information on the sale and redistribution of select controlled substances. Whether and how the substances are eventually prescribed to consumers, and whether those prescriptions are filled, is not information contained in the ARCOS system. ARCOS also does not include information on every opioid product.

2. **What is the largest hurdle you face as your companies scale up your diversion prevention activities? Is data-sharing, or lack thereof, the primary challenge?**

Data-sharing is certainly one of the major challenges to anti-diversion efforts, but it also represents an opportunity. Anti-diversion efforts of Controlled Substance Act registrants all along the supply chain, from manufacturers to distributors, providers, and pharmacists, would benefit from increased data sharing among one another and with the DEA. Programs such as a prescription safety alert system could provide information about a patient's nationwide prescribing history to identify abuse or misuse. As described above, more complete access to the DEA's ARCOS data could also be a valuable anti-diversion tool. Clearer definition of the roles, responsibilities, and expectations of each registrant could also generate better results.

3. **Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?**

Each registrant under the Controlled Substances Act has a role to play in preventing diversion, as does the DEA. McKesson's Controlled Substance Monitoring Program ("CSMP") can help to identify potentially suspicious orders. However, McKesson does not have full visibility into the actions of prescribers, pharmacies, patients, or the other distributors. DEA has the most complete information, and only DEA has the ability to conduct law enforcement investigations of reported suspicious ordering activity. McKesson supports the DEA in those efforts when asked. McKesson respectfully defers to the DEA on what the DEA does with the suspicious order information the company reports.[2]

4. **Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?**

McKesson has released a comprehensive set of proposals that it believes would help address the opioid crisis. These are available at http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/opioid-policy-recommendations/. Enclosed with this letter

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[2] McKesson assumes for purposes of this response that the question was intended to read, "Where is the line drawn between drug *distributors* and the DEA in responding to suspicious orders?"

are copies of McKesson's 2017 white paper, *Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions*, and McKesson's 2018 white paper, *Call to Action: Execute Solutions Today to Combat the Opioid Crisis.*

The Honorable David B. McKinley

1. **As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74**

DEA regulations require registrants to identify and report suspicious orders when discovered. McKesson complies with this regulation using complex data analytics to set and manage customer thresholds for controlled substances. McKesson's model analyzes each customer order against its applicable threshold to determine whether the order should be filled. If a customer's order exceeds the applicable monthly threshold, that order is blocked and not filled. McKesson reports all such orders to DEA pursuant to 21 C.F.R. § 1301.74.

2. **Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?**

No. McKesson only ships controlled substances to pharmacies that are registered with the DEA and licensed by their respective state to receive such products. As a distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

3. **In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?**

No. As noted above, McKesson only ships controlled substances to pharmacies that are registered with the DEA and licensed by their respective state to receive such products. As a distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

4. **Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?**

No. As stated previously, McKesson supplies controlled substances only to those pharmacies that are registered with DEA and licensed by their respective states. As a

distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

5. **Do you agree the United States is in the midst of a prescription opiate epidemic?**

McKesson agrees and believes that many players in the pharmaceutical supply chain, medical community, and government will be needed to help bring an end to prescription drug abuse. To that end, beyond its various CSMP activities and anti-diversion efforts, McKesson has published multiple white papers containing proposals aimed at combatting drug diversion. In addition, McKesson has established and committed $100 million to a new non-profit foundation dedicated to combatting the opioid crisis.

6. **Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?**

No. As stated previously, McKesson supplies controlled substances only to those pharmacies that are registered with DEA and licensed by their respective states. As a distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

7. **Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?**

The country is in the midst of a serious opioid abuse problem. It is a multi-faceted problem that must be addressed through a comprehensive approach. McKesson has published a range of public policy recommendations aimed at combatting the opioid abuse problem.

8. **Do you believe the prescription opiate epidemic is a public nuisance?**

The opioid epidemic is a terrible problem faced by many families and communities in this country. McKesson is committed to working with Congress and other stakeholders to find effective means to combat the problem of prescription drug abuse. But as a legal matter, the answer to your question is no.

9. **Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?**

McKesson has devoted significant resources to make key enhancements to its CSMP, including strengthening our compliance team, customer diligence efforts, ongoing oversight, suspicious order reporting, and customer education efforts. McKesson has also devoted significant resources to the development and implementation of advanced analytics to monitor orders for controlled substances, including those placed by pharmacies in West Virginia.

10. **Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?**

McKesson has made a number of enhancements to its CSMP and reporting practices, including its reporting practices with respect to the West Virginia Board of Pharmacy. If a customer order for a controlled substance exceeds established monthly thresholds, the order is blocked and reported to DEA and to the West Virginia Board of Pharmacy.

11. **Did your company have a policy that orders had to be less than 50% controlled substances to be filled?**

McKesson's CSMP includes a tool that allows the company to analyze a pharmacy's controlled substance ordering ratio over time, and that information can be a data point in decisions about whether to bring on the pharmacy as a new customer or change the ordering thresholds for a current customer. Because each pharmacy's situation is unique, McKesson believes that the company's advanced analytics system is a more appropriate tool for identifying suspicious ordering activity than a fixed ratio.[3]

The Honorable Frank Pallone, Jr.

1. **Prior to August 2013, McKesson was not regularly reporting suspicious order reports to DEA as required. When DEA Administrator Robert Patterson testified before the Committee in March, he stated that when distributors fail to report suspicious orders to DEA, it is much harder for DEA to do its job. Do you agree that timely reporting of suspicious orders plays a key role in preventing diversion?**

McKesson has reported hundreds of thousands of controlled substance orders to DEA as suspicious pursuant to 21 C.F.R. § 1301.74. McKesson is not aware of evidence that those reports are used by DEA to generate investigative leads. McKesson has for many years reported orders to DEA through ARCOS. According to DEA's website, "ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and

[3] As for a ratio requiring individual orders to be less than 50% controlled substances, such a policy is not feasible. Federal regulations require that some orders containing controlled substances not include any non-controlled substances in the order.

state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). [sic] by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts."[4]

2. **You testified that McKesson's order monitoring systems "determine a suspicious order based primarily on quantities compared to average pharmacies, pharmacies that are similar." However, McKesson shipped Sav-Rite pharmacy in Kermit, WV, population 400, 4.8 million hydrocodone pills in 2006 and 2007. According to data cited by DEA, that was approximately 8 times the amount of hydrocodone that an average rural pharmacy in West Virginia would have expected to receive. What failed in McKesson's suspicious order monitoring system to allow such large quantities of opioids to ship to this pharmacy?**

McKesson's current CSMP utilizes a threshold management system to monitor orders of controlled substances and block and report all orders exceeding that threshold. McKesson's customer thresholds are set using complex analytics that take into account, among other factors, pharmacy size and a comparison to pharmacies of similar size. Orders that exceed monthly thresholds are blocked and not shipped. Those blocked orders are reported to DEA as suspicious pursuant to 21 C.F.R. § 1301.74.

3. **Considering the opioid crisis in West Virginia, what more could McKesson have done to monitor the opioid shipments it was sending to these communities?**

As described above, McKesson is firmly committed to having in place effective policies and procedures to monitor its distribution of controlled substances across the country, including West Virginia, and has continued to enhance its program. Moving forward, McKesson hopes that there will be greater coordination, cooperation, data sharing, and knowledge sharing among the industry, DEA, and state boards of pharmacy.

4. **When McKesson acquires a smaller wholesale distribution company, what type of due diligence does McKesson perform on the pharmacy customers previously served by the acquired distribution company? Is it McKesson's practice to perform a new customer intake examination of each pharmacy that has elected to use McKesson as its new wholesaler? If so, for how long has this been McKesson's policy? Does McKesson inspect the due diligence files maintained by the acquired wholesaler for each transferred pharmacy customer? If so, for how long has this been McKesson's policy?**

While this type of acquisition is infrequent and atypical, when McKesson acquires customers through the acquisition of another distributor, it validates the registration and

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[4] *See* https://www.deadiversion.usdoj.gov/arcos/index.html (last visited June 6, 2018).

licensure status of each of the target company's pharmacy customers that will be supplied controlled substances after the acquisition. To the extent the newly acquired pharmacy customers will be supplied controlled substances, such distribution will be subject to the applicable requirements of McKesson's Controlled Substance Monitoring Program, including its system of monthly thresholds limiting the amount of controlled substances the pharmacy customer can purchase.

The Honorable Jan Schakowsky

1. **How much does McKesson net annually for its distribution of Evzio?**

McKesson does not generally track profits by molecule for products in its branded and generic pharmaceutical units.

2. **McKesson also distributes Narcan. What does McKesson earn net per unit for Narcan?**

McKesson does not generally track profits by molecule for products in its branded and generic pharmaceutical units.

3. **How much does McKesson net annually for its distribution of Narcan?**

McKesson does not generally track profits by molecule for products in its branded and generic pharmaceutical units.

4. **As early as 2007, a CDC memorandum showed that West Virginia drug overdose deaths increased by 550 percent between 1999 and 2004. Despite these reports, McKesson was providing millions of opioid pills to a single pharmacy in Kermit, West Virginia. Did McKesson understand there was a serious diversion problem facing the state, and how could McKesson have improved its handling of controlled substances?**

As described in McKesson's written response to the Committee, in 2007 McKesson implemented a new controlled substance monitoring program, and further enhanced that program in 2008 following its settlement with DEA. McKesson is firmly committed to having in place effective policies and procedures to monitor its distributions of controlled substances across the country, including West Virginia. Moving forward, McKesson hopes that there will be greater coordination, cooperation, data sharing, and knowledge sharing among the industry, DEA, and state Boards of Pharmacy.

5. **Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?**

In most instances, McKesson buys drugs from manufactures, takes title upon delivery to McKesson facilities, and transfers title upon delivery to the customer.

6. **In setting prices to pharmacies, is your markup more like a flat rate (for example, selling $5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?**

McKesson determines pricing for all pharmaceutical products, including controlled substances, on an individual customer basis determined by factors specific to that customer, including the customer's overall product mix. The system is not as simple as buying a product from a manufacturer and selling it to customers at a markup. Although the specifics vary by product, McKesson's business model involves purchasing product from the manufacturer; charging the manufacturer a fee for service on the product; earning rebates and similar benefits from the manufacturer based on product ordering; and charging the customer a percent of the original acquisition costs. Depending on the product, McKesson may charge the customer more or less than McKesson paid to acquire the product from the manufacturer.

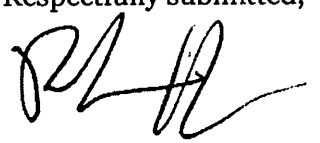
7. **Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?**

As described above, McKesson's sales model is not as simple as reselling products at a markup. McKesson may make either more or less when the acquisition price of a product increases. Put another way, McKesson does not benefit from every price increase by a manufacturer, and often is required to return to the manufacturer the benefit of the manufacturer's price increase.

* * *

McKesson appreciates this opportunity to respond to the Committee's questions. Please let us know if you require additional information.

Respectfully submitted,



Robert K. Kelner

Encl.

MCKESSON

Combating the Opioid Abuse Epidemic:

A Shared Responsibility that Requires Innovative Solutions

March 2017

Every day, the opioid abuse epidemic affects communities across America. This white paper presents McKesson's recommendations to improve prescribing and dispensing practices towards our country's shared goal: to eliminate the detrimental impact of the opioid abuse epidemic. Our recommendations include the following:

- Require all payers and providers to use opioid management programs
- Require e-prescribing for all controlled substances
- Harness the Food and Drug Administration's Risk Evaluation and Mitigation Strategies Program
- Fully leverage data analytics to identify patients most at risk and integrate a National Patient Safety Network into the pharmacy dispensing process
- Improve information sharing among Prescription Drug Monitoring Programs
- Permit partial refills to reduce risks associated with an excess of unused pills

The white paper also highlights McKesson's efforts to promote a secure supply chain and educate and equip our customers, physicians and pharmacists. As healthcare reform and other issues capture headlines, we must continue to do all we can, together, to combat this public health challenge.

Public Affairs
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The Crisis

Our country is in the midst of a serious opioid abuse epidemic, which is affecting every community in America. It has claimed victims from all races, ages, and socio-economic groups. According to the Centers for Disease Control & Prevention (CDC), from 2000 to 2014, nearly half a million Americans died from drug overdoses.[1] In 2015, more than 15,000 people died from overdoses involving prescription opioids.[2] Additionally, each day over 1,000 people are treated in emergency departments for not using prescription opioids as directed.[3] The National Institute on Drug Abuse (NIDA) has cited the increased volume of opioid prescriptions as a driving factor for the severity of the current crisis.[4]

The opioid epidemic is a multi-faceted problem that cannot be solved by focusing on individual parts of the healthcare system. It must be addressed through a comprehensive approach that includes the doctors who write the prescriptions, the pharmacists who fill them, the distributors who fill and deliver pharmacies' orders, the manufacturers who make and promote the products, and the regulators who license the above activities and determine supply.

McKesson is fully committed to working with all stakeholders to protect the supply chain and help prevent diversion while ensuring appropriate treatments are available to patients. With a 360-degree view of healthcare and customers across industry and government, McKesson is uniquely positioned to advocate for a comprehensive set of policy and business solutions that will harness the power of technology to promote improved prescribing and dispensing. The implementation of these policy and business solutions could significantly slow the abuse and diversion of opioids, to the benefit of patients and their families.

Current Initiatives and Proposals

Policymakers, manufacturers, insurers, and other stakeholders have launched numerous initiatives and proposed a wide range of policies aimed at curbing misuse of opioids, including pill disposal requirements, product stewardship, enhanced provider and pharmacist education, Medicare beneficiary "lock in," and various pill limitation measures.

In January 2016, the **Centers for Medicare & Medicaid Services (CMS)** released its opioid management strategy, which outlines the agency's plan to address the national opioid epidemic. The strategy features four key policy areas[5]: (1) implementing more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion; (2) expanding naloxone (an overdose reversal drug) use, distribution, and access, when clinically appropriate; (3) expanding screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment; and (4) increasing the use of evidence-based practices for acute and chronic pain management.

The Department of Veterans Affairs (VA) has engaged in a comprehensive approach aimed at reducing the use of opioids among veterans using VA healthcare.[6] The VA's Opioid Safety Initiative (OSI) is an effort to improve the quality of life for veterans suffering from chronic pain. The program features patient management initiatives including Pain Coach, which is a pain management application available for download by patients receiving pain management treatments, a Veterans' Health Library, a Patient/Family Management Toolkit, and resources for Pain Management on My HealtheVet. All of these applications allowed veterans to better manage their pain without the use of opioids.[7] The VA has also been on the leading edge of PDMP interoperability, naloxone distribution, drug take back and opioid management programs.

In July 2016, **Congress** passed the Comprehensive Addiction and Recovery Act of 2016 (CARA) with overwhelming bipartisan support. CARA focuses primarily on treatment, recovery, law enforcement, criminal justice reform, and access to overdose reversal drugs.

Also in July 2016, the **National Governors Association (NGA),** released a resource for state governments to address the opioid epidemic, titled *Finding Solutions to the Prescription Opioid and Heroin Crisis: A Road Map for States.*[8] *A Road Map for States* is a thoughtful and comprehensive set of evidence-based public policy recommendations and public health strategies focused on prevention and response to opioid misuse and overdose.

These are all thoughtful steps in taking meaningful action to combat the scourge of opioid abuse and diversion; and yet, there is more work to be done.

McKesson's Public Policy Recommendations

Patients taking prescription opioids interact with the healthcare system at least twice in order to access their medications. The first interaction takes place when the prescriber writes a prescription, and the second interaction takes place at the pharmacy when the prescription is dispensed to the patient. There are significant opportunities to engage at both encounter points to ensure that opioids are being prescribed and dispensed in an appropriate manner.

The proposals outlined below are aimed at establishing mechanisms to improve clinical treatment decisions by providing better information at the point of prescribing. Also included are a complementary set of policies that would similarly deliver actionable information to dispensing pharmacists.

Section 1: Improve Prescribing Practices for Opioids

In some instances, patients can obtain inappropriate access to prescription opioid medication by manipulating the prescription process. For example, some patients are able to interact with multiple doctors or pharmacies to acquire opioids that may not be clinically necessary. Multiple strategies can be deployed to improve opioid prescribing practices. Implementing e-prescribing requirements can limit opportunities for individuals to forge paper prescriptions for opioids. Providing comprehensive, accurate, and up-to-date information about a patient's prescription utilization history would significantly improve a physician's ability to identify instances where prescribing an opioid may be inappropriate. Additionally, improving and enhancing provider education about when and how to prescribe opioids, as well as recognizing any potential abuse, and the ability to carefully review a patient's prescription history – all would enhance the safety of prescribing practices.

Recommendation 1: Require all payers and providers to use opioid management programs

Many public and private health plans, pharmacy benefit managers (PBMs), and hospital and physician organizations have adopted opioid management programs to curb overprescribing, misuse, and abuse. These programs often combine multiple strategies to improve decision-making when prescribing opioids and incorporate evidence-based clinical guidelines. A number of payers have adopted the CDC clinical guidelines for prescribing opioids, released in March of 2016. By the end of 2017, 21 states will use these guidelines for Medicaid fee-for-service and 11 states will require that Medicaid managed care organizations adopt them.[9] McKesson supports broader awareness and adoption of the CDC and other evidence-based clinical practice guidelines. We believe embedding these guidelines at the point of care (e.g., integration into e-prescribing, electronic health records, or other care management processes) can improve prescribing practices both in workflow and at the right time along the care continuum.

Several opioid management programs have had promising results. The emerging model implemented by Blue Cross Blue Shield of Massachusetts (BCBS-MA) is reporting successful outcomes and can serve as a model for other stakeholders to consider. Over a three-year period, the BCBS-MA program reduced the risk of substance use disorders and other health issues related to long-term use of opioids. The program eliminated an estimated 21.5 million doses of opioid-based medications in the communities served by its plans and reduced claims for long-acting opioids by approximately 50 percent by switching patients to short-acting pain treatments.[10]

Key elements of the program include, but are not limited to: (1) a comprehensive treatment plan between doctor and patient that outlines the expectations of both parties and considers non-narcotic treatment options; (2) a clinical risk evaluation for addiction that is signed by the patient; (3) choosing a single pharmacy or pharmacy chain to be used for all opioid prescriptions; (4) a prior authorization requirement for all new short-acting opioid prescriptions for more than 30 days and for all new long-acting opioid prescriptions; and (5) a three-day supply of short-acting opioids if prior authorization isn't immediately available, allowing time for authorization.

The BCBS-MA program features effective patient safety measures while ensuring access to care for patients in need. Cancer patients and terminally-ill patients are exempt from many of the authorization requirements, which is important for every opioid management program to contemplate since it is estimated that pain occurs in up to 70 percent of patients with advanced cancer.[11] Requiring a broader adoption of the key elements of BCBS-MA's opioid management programs could have a significant impact on the national opioid epidemic.

Recommendation 2: Require e-prescribing for all controlled substances

Traditional handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to prescription opioids.[12] Electronic prescribing (e-prescribing) allows prescriptions to be transmitted to pharmacies

securely without risk of alteration or diversion, and prescribers can be authenticated before dispensing of controlled substances and prescriptions. The American Journal of Pharmacy Benefits (AJPB) has recommended e-prescribing to help address the misuse and diversion of opioid medications.[13] E-prescribing of controlled substances (EPCS) is currently permitted in all 50 states, yet is only required in New York, Maine, and Minnesota. There is significant variability across the states in terms of e-prescribing capabilities and behaviors, and not all pharmacies or physicians' offices are capable of transmitting prescriptions electronically.[14] For example, in 2015, 82% of pharmacies in Nebraska were EPCS-enabled, along with 15% of prescribers.[15] By contrast, for the same year in Florida, 74% of pharmacies were EPCS enabled along with only 2% of prescribers.[16] Nationally, just 8% of physicians serve in practices that allow for the use of this technology to prescribe controlled substances like opioids.[17] Research on EPCS has been scarce, but surveys have shown that prescribers are generally optimistic about the benefits of EPCS.[18] A nationwide e-prescribing requirement for opioids could be a promising solution for reducing forged prescriptions and strengthening the efficacy of state prescription drug monitoring programs (PDMPs) across the country.

Recommendation 3: Harness FDA's Risk Evaluation and Mitigation Strategies (REMS) Program
The Food and Drug Administration (FDA) recognizes that there are risks associated with the use of certain drugs or classes of drugs. In order to manage these risks, the FDA requires drug manufacturers to create risk evaluation and mitigation strategy programs, or REMS, which include activities such as creating a medication guide and communication plan for healthcare professionals and distributors. These initiatives can help identify potential risks, harmful drug interactions, and other guidelines for safe use and proper disposal of opioids. Given the potential safety risks associated with opioids, the FDA has a class-wide REMS policy for all extended release and long acting (ER/LA) opioids. However, not all long-acting opioids have been subject to REMS requirements. The FDA recently announced that it intends to require a REMS for all forms of opioids to "ensure the benefits of these drugs continue to outweigh the risks of misuse, abuse, addiction, overdose and death."[19] McKesson supports the FDA's initiative.

The impact of opioid REMS has been hindered by low awareness of, and limited participation in, the physician education programs offered by drug manufacturers. For example, the voluntary REMS for ER/LA opioids fell short of its targeted prescriber goal. In the first two years, 37,512 prescribers completed the training, accounting for just under half (47 percent) of the targeted 80,000 prescribers.[20] A recent PriMed study involving 441 healthcare providers that received REMS training and 4,669 providers that were not trained, found that those who had REMS training had a 10% drop in ER/LA prescribing compared with a 4% increase in the untrained population.[21]

To improve effectiveness of the opioid REMS program, McKesson recommends: (1) implementing REMS requirements for all long-acting opioids as soon as possible; (2) increasing provider participation in REMS educational activities; and (3) improving the educational programs associated with REMS requirements and beyond. An exemption should be granted for cases in which a physician cares for a patient with a terminal condition, since certain REMS requirements (e.g., requiring physicians to document that terminally-ill patients understand the risk of addiction and abuse) could contribute to the patient avoiding the medication due to fear of addiction.

Section 2: Improve Dispensing Practices for Opioids

Dispensing pharmacists are a strong second line of defense to detect potential opioid abuse or misuse. Unlike prescribers who often do not engage with patients during refills, pharmacists handle refill prescriptions and the interaction with patients. Therefore, they must be a part of the solution. To maximize a dispenser's ability to identify potential instances of fraud or opioid misuse, it is vital that pharmacists and their staff have easy access to reliable, up-to-date information about a patient's prescription history. Further, to minimize the risk of opioid misuse, patients must not be prescribed more medication than they will need to manage their medical conditions.

Recommendation 4: Integrate a National Patient Safety Network into the pharmacy dispensing process
Under the current system, which the National Council for Prescription Drug Programs (NCPDP) describes as "systematically burdensome," pharmacists must leave their workstations to check a PDMP.[22] Unsurprisingly, research indicates that pharmacists do not always consult PDMPs. For example, a survey of pharmacists in Maine found that, in 2014, only 56 percent were using the state's PDMP.[23] Delivering alerts through the very same system that pharmacists use as part of their dispensing process would save significant time and, most importantly, would increase the likelihood that pharmacists consult their PDMPs.

To make the most informed dispensing decisions, pharmacists need access to robust, real-time information that can access and analyze data across all 50 states. One tool that can be used to increase patient safety is an automated,

clinically-based system that notifies dispensers in real-time and in workflow when a drug may present a safety issue to a patient (e.g., non-medical use, miscalculated dosage, or drug interactions).

This tool, a National Patient Safety Network ("Network"), as envisioned by NCPDP would identify "red flags" and alert dispensers whenever patient safety issues are identified. For example, in instances where there may be non-medical use of opioids, the Network would notify the pharmacist who could *voluntarily* check the PDMP before dispensing. The Network would complement PDMPs in two significant ways by: (1) providing alerts to dispensing pharmacists that are based on real-time, comprehensive prescription history data for patients, regardless of setting of care, and (2) promoting more effective use of PDMP information since pharmacists would know when to consult the PDMP rather than having to check it for all patients.

The Network could also benefit physicians, who according to a 2014 survey cited the time-consuming nature of retrieving data from PDMPs as a barrier to their use.[24] The same survey found that while doctors prescribed opioids for an average of 35 patients a month, they retrieved data from a PDMP for an average of only eight patients a month.[25] The NCPDP solution proposes that all electronic prescriptions, as well as all pharmacy dispensing activity, are evaluated against the Network.

Recommendation 5: Improve information sharing among PDMPs

PDMPs are an important tool for pharmacists who serve as a crucial line of defense in identifying and avoiding potential opioid misuse and abuse. However, the data in PDMPs are typically limited to the prescription data from within the state the pharmacist is operating in. This means that a pharmacist searching a PDMP in one state may not have access to data from another state's PDMP. The data collected by PDMPs vary by state[26] and, according to a December 2016 report by Pew Charitable Trusts, data sharing between PDMPs is often slow.[27] Establishing a mechanism to exchange opioid prescription data across all state PDMPs would enable standardized data to be shared on a real-time basis. For example, a system like the one envisioned by CommonWell® Health Alliance, a vendor-neutral platform that breaks down barriers that currently inhibit effective, interoperable exchange of health data, would enable prescribers and dispensers to access comprehensive data from PDMPs from across the country that captures all opioid prescription activity, regardless of setting of care. The Network described above can provide PDMPs more robust real-time data, if states elect for that data to be incorporated into their PDMPs.

Recommendation 6: Permit partial refills to reduce risks associated with an excess of unused pills

Prior to 2016, as Schedule II products, opioid prescriptions were not permitted to be refilled. This may have led some prescribers who anticipate an increased need for pain management in patients with acute pain to prescribe a greater supply of medication than necessary. This practice has resulted in an excess of unused pills. According to a study by the Johns Hopkins Bloomberg School of Public Health, six out of 10 adults prescribed opioid painkillers have leftover pills.[28] Allowing patients to partially refill their prescriptions increases the chances that a patient will be prescribed the exact number of pills that he or she needs, thereby reducing the risk of these "extra" pills being improperly disposed, lost, stolen, sold or given to others.

States and federal lawmakers have begun to take action aimed at limiting the risks associated with excess pills. For example, New Jersey recently enacted a law that imposed a five-day limit on a patient's first opioid prescription.[29] At the federal level, CARA permits a prescription for a Schedule II controlled substance to be partially filled if: (1) it is not prohibited by state law; (2) the partial fill is requested by the patient or the practitioner who wrote the prescription; and (3) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.[30] Providing flexibility to allow patients and prescribers to reduce the number of unused opioid pills limits opportunities for diversion or misuse of these medications. A swift and comprehensive implementation of this policy, along with proper coordination with the states, can reduce the volume of unused pills and the risk of diversion and misuse.

Section 3: Our Efforts

McKesson understands that thoughtful and innovative public policy solutions alone are not enough. We are committed to working closely with our partners and customers to fight the opioid abuse epidemic.

Promoting a Secure Supply Chain

McKesson plays an important role in the proper disposal of medication. We are committed to ensuring unused medications are properly collected from our customers and our distribution centers and safely processed out of the supply chain. Over the last three years, we have worked with reverse distributors to appropriately dispose of, and in many instances, recycle, an average of 7.2 million products a year. In addition, we leverage our unique relationship with our customers to educate pharmacists about medication disposal so they in turn can educate their patients.

McKesson provides its Health Mart® pharmacists with "Drug Take Back Solutions" information, which demonstrate how they can partner with local law enforcement in getting unwanted or expired medications off the street.

McKesson operates a robust Controlled Substances Monitoring Program (CSMP) to help us identify and report suspicious orders. We also are utilizing advanced analytical tools to closely monitor our customers' purchases. We are committed to continuing to make enhancements as needed to ensure our CSMP remains an effective contribution in our country's battle with opioid diversion and abuse.

Educating Our Customers

An FDA advisory panel has endorsed mandatory training for doctors who prescribe opioids as part of the efforts to stem the national epidemic of deaths and addiction related to these drugs. McKesson supports improvements in both formal medical education and continuing medical education to better inform clinical practice in pain management. MedTrainer, a compliance and regulatory training tool offered to McKesson's provider customers, provides training opportunities focused on responsible opioid prescribing and on recognition of drug seeking behavior and substance abuse disorders.[31]

Similarly, McKesson provides its nearly 5,000 HealthMart® independent community pharmacies with relevant information, tools, and resources about prevention of opioid abuse. As independent business owners, Health Mart® members are empowered to become advocates for drug abuse prevention in their communities, starting with their own pharmacies. All HealthMart® pharmacies are equipped with the *Health Mart Operations Toolkit*, an online portal where pharmacists can access resources created specifically to help prevent drug abuse in their communities, including: (1) education and training courses available for the entire pharmacy's staff; (2) drug abuse prevention solutions, which contains news, drug take back solutions, education, and outreach ideas; (3) best practices and practical advice for pharmacists and technicians to prevent drug abuse when filling prescriptions; and (4) community outreach resources with strategies to promote drug abuse prevention at the local level.

Conclusion

Absent thoughtful and innovative solutions, the disturbing impact of opioid abuse and misuse will continue unabated. Meaningful solutions require the partnership of a variety of stakeholders, including doctors, pharmacists, distributors, manufacturers, payers, policymakers, and regulators. We believe the innovative solutions presented above offer a practical and unique approach to both the improvement of prescribing and dispensing practices and processes.

As a company, we are committed to advancing impactful solutions and continuing to innovate in our own processes. We stand ready to collaborate with lawmakers and all stakeholders and partners in the pharmaceutical supply chain to address our nation's devastating opioid abuse epidemic. For more information or to partner with McKesson Public Affairs on these policy solutions, contact PublicAffairs@McKesson.com.

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McKESSON

Call to Action: Execute Solutions Today to Combat the Opioid Crisis

McKesson's Recommendations to Combat the Opioid Crisis

The opioid epidemic continues to affect communities across America. Our prioritized set of recommendations focus on enhancing clinical knowledge and leveraging data and technology solutions across the care continuum to address overprescribing and dispensing and enable real-time solutions to identify at-risk patients.

Key recommendations include:

- Implement a prescription safety-alert system to provide pharmacists and ultimately doctors with real-time alerts to identify at-risk patients
- Incentivize implementation of opioid stewardship or similar clinical excellence programs
- Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives
- Require electronic prescribing (eRx) of all controlled substances
- Require use of electronic prior authorization (ePA) to better align prescribing with best clinical practices, prevent misuse, and ensure access for patients with legitimate need
- Pilot pharmacist-led opioid care management programs

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Introduction

Our country's opioid epidemic has continued to affect communities throughout the country. It has claimed victims from all races, ages, and socio-economic groups.

The opioid epidemic is a complex, multi-faceted problem that cannot be solved by focusing on one part of the system or stakeholder. Rather, solutions must be comprehensive and should include, among others:

- the doctors who write the prescriptions,
- the pharmacists who fill them,
- the distributors who deliver the pharmacists' orders,
- the manufacturers who make and promote the products,
- the payers who make reimbursement decisions,
- and the regulators who license the above activities and determine supply.

More must be done, starting with acting on the recommendations we've proposed in this paper.

Every day, our company and our people work hard to ensure that appropriate treatments are available to patients in need. We remain steadfast in our commitment to work with all stakeholders to protect the supply chain and prevent diversion while ensuring that patients who need their medicines get them in a timely manner. With customers across the healthcare industry and government, we have a unique view of the healthcare ecosystem. That's why we'll continue to advocate for policy recommendations and technology-driven ideas that we strongly believe can slow the abuse and diversion of opioids, and most important, help to end this national crisis.

As the opioid epidemic persisted, we wanted to help the healthcare system look at holistic ways to combat the problem. That's why in 2015, we created an internal task force of experts, including clinicians, technologists, and public policy experts. In March 2017, McKesson released our policy paper, Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions. It included policy recommendations in six major areas that we believe will help curb the opioid epidemic.

In this paper, we expand upon our 2017 policy recommendations, identify additional opportunities for appropriate intervention and describe approaches for comprehensive, integrated solutions to address the opioid epidemic across the healthcare ecosystem. Our new set of policy recommendations included in this paper continues to reinforce the need for public and private partnerships that:

- Promote patient-centered solutions,
- Foster clinical collaboration across the care continuum, and
- Bolster leadership and accountability.

For a full listing of McKesson's efforts to combat the opioid crisis, please visit: www.mckesson.com/about-mckesson/fighting-opioid-abuse/

Overview of McKesson's New Public Policy Recommendations

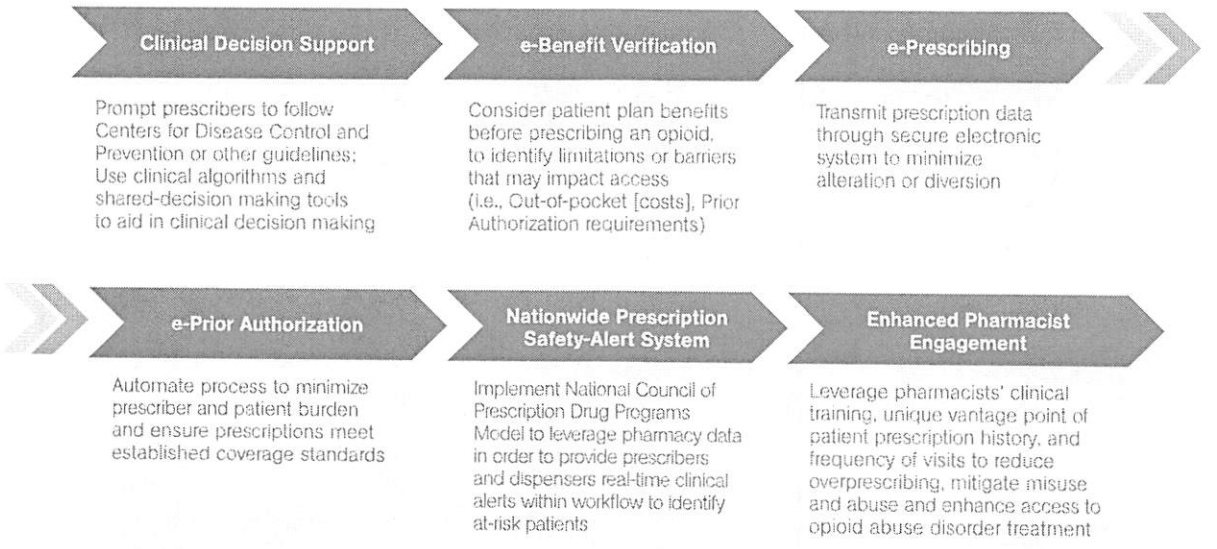
It is critical that we drive a culture of change that embraces a team-based approach to comprehensive pain management. This requires coordination across all stakeholders that impact the supply chain and those on the front lines of care delivery. Data and technology solutions must be thoughtfully deployed to ensure that necessary data flows through the healthcare system, enabling clinicians to meet the diverse needs of patients. However, this cannot be done until stakeholders collectively agree to utilize the tools at our fingertips to modernize the way opioids are prescribed and patients are managed across the care continuum.

The recommendations laid out in the next section, "McKesson's Prioritized Public Policy Recommendations," focus on enhancing clinical knowledge and leveraging data and technology solutions across the care continuum to address overprescribing and dispensing, while enabling real-time technology solutions to reduce supply and identify at-risk patients. We also advocate for additional policy changes that we believe can play a significant role in ending the opioid epidemic.

Details of our full set of 2018 recommendations can be found in Appendix A.

A comprehensive list of our 2017 and 2018 recommendations can be found in Appendix B.

Enable Real-Time Solutions to Reduce Supply and Identify Patients at Risk



McKesson's Prioritized Public Policy Recommendations

We recognize that modernizing the approach to pain management and opioid prescribing should be driven by enhancing clinical knowledge, understanding prescribing best practices, and using tools and technological solutions to assist in clinical decision making and patient engagement. We believe our policy recommendations can be implemented today and can have an immediate impact in curbing the opioid crisis.

Clinical Decision Support

Independent medical experts have advised that appropriate opioid prescribing is built upon comprehensive pain management knowledge, understanding of opioid prescribing guidelines, and effective patient engagement. However, most opioids are not prescribed by pain specialists. Rather they are prescribed by primary care physicians, internists, dentists, and orthopedic surgeons.[1] While technology embedded within the electronic health record may prompt the clinician with relevant information, we think it is important to ensure clinical behaviors are driven by an expanded knowledge of comprehensive pain management, rather than simply reducing opioid prescriptions. In addition to constraining supply through initiatives such as limiting initial fills, our recommendations seek to increase clinical knowledge and improve patient engagement.

Recommendations:

- Implement nationwide prescription safety-alert system that may be used by pharmacists, and ultimately by prescribers, to inform clinical decision making (details on page 5)
- Incentivize implementation of opioid stewardship or similar clinical excellence programs
- Require all prescribers to participate in approved clinical training and continuing medical education as condition of licensure
- Deploy in-person prescriber training programs to reduce overprescribing

Electronic (e)-Benefit Verifications

Use of pharmacy benefit verification tools allows providers to have a more complete picture of a patient's insurance coverage and any limits the payer may have on opioids and alternative treatments, including supply limits and mandatory prior authorizations. These tools also increase cost transparency. They can enable an open discussion between providers and patients on the impact cost may have on treatment selection. Use of e-benefit verification tools provide prescribers a unique opportunity to discuss the risks and benefits of opioid use, as well as clinically appropriate treatment alternatives. We strongly believe in the value of these solutions. We encourage all prescribers to utilize such tools to increase shared-decision making, and improve adherence and patient knowledge on the risks of opioid addiction.

Recommendations:

- Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives, at the time of prescribing and on a consistent basis

Electronic Prescribing (eRx)

Handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to prescription opioids. Moreover, paper prescriptions make it difficult to identify prescribing trends. eRx allows prescriptions to be transmitted to pharmacies securely while minimizing the risk of alteration or diversion. eRx also allows for data analytics and trendspotting regarding opioid prescribing. eRx of controlled substances (EPCS) is currently permitted in all 50 states, yet is only required in a few. Research on EPCS has been scarce, but surveys have shown that prescribers are generally optimistic about its benefits.[2] Because utilization of eRx is still modest despite it being allowed in all states, the use of mandates has become necessary to curb the epidemic.

Recommendations:

- Implement mandatory eRx of opioids under Medicare Part D as proposed in pending federal legislation and in some states
- Strongly encourage private payers to adopt similar policies

Electronic Prior Authorization (ePA)

Employers and payers have implemented programs to detect and intervene in inappropriate prescribing of opioids. Prior authorization (PA), a process to verify that medications or procedures are medically necessary, is used by payers before they grant coverage approvals.[3] A study of Medicaid patients

in Pennsylvania found that enrollees within plans that subject opioids to PA policies had lower rates of abuse and overdose after initiating opioid medication treatment.[4] While the use of PA is frequently associated with reductions in use of opioids, traditional PA – most often completed via handwritten faxed forms or phone calls – can frequently place significant burdens on physicians, pharmacists, and patients who legitimately need prescription painkillers to manage their conditions.

Recommendations:

- Require use ePA of opioids under Medicare Part D as proposed in pending federal legislation
- Require use of ePA for opioids and other drugs as proposed in several state proposals
- Strongly encourage private payers to adopt similar policies

Nationwide Prescription Safety-Alert System

We strongly support the implementation of a nationwide prescription safety-alert system, a model conceived by the National Council for Prescription Drug Programs (NCPDP) and recently cited by the Duke Margolis Center for Health Policy.[5] The prescription safety-alert system would use patient prescription history data and clinical rules to identify patients and prescription patterns that may indicate risks of opioid overuse, abuse, addiction or misuse. Pharmacies would receive real-time alerts in workflow indicating that the pharmacist should gather additional patient information before dispensing. This might include a more in-depth conversation with the patient, a consultation with the prescribing physician(s), and review of the relevant state PDMP data. To maximize success, the prescription safety-alert system must have access to data from all entities dispensing covered controlled substances. e-prescribing would facilitate prescriber access to the prescription safety-alert system.

Recommendation:

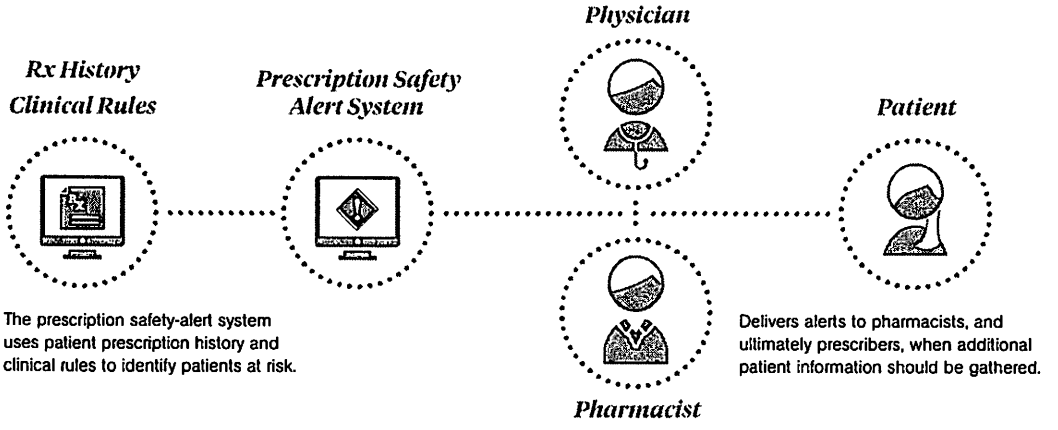
- Health and Human Services/Food and Drug Administration, through its existing Risk Evaluation and Mitigation Strategy authority, should require that manufacturers only provide covered controlled substances to pharmacies and healthcare providers that participate in a prescription safety-alert system

Enhanced Pharmacist Engagement

According to the Johns Hopkins Bloomberg School of Public Health, "community pharmacy remains the 'untapped resource' for the national opioid epidemic." Furthermore, the U.S. is also in the early stages of another looming public health crisis – a projected physician shortage of over 100,000 physicians by 2030, due to a growing and aging population.[6] In addition, every year, roughly one out of every four substance-abuse clinicians nationally leaves the profession.[7] Total pharmacist employment, on the other hand, is projected to grow by almost 18,000 jobs by 2026.[8] Given our country's current opioid crisis, impending physician shortage crisis, and the availability of highly skilled, medically-trained pharmacists that can help now, pharmacists must be better equipped to fight against the epidemic.

Recommendations:

- Pilot pharmacist-led opioid care management models
- Allow pharmacists to participate in and be reimbursed for Screening, Brief, Intervention and Referral to Treatment (SBIRT) activities
- Expand access to Medication-Assisted Treatment (MAT) by allowing pharmacists to provide and be reimbursed for MAT
- Increase access to opioid overdose antidotes, such as naloxone, by allowing pharmacists to dispense and be reimbursed for such treatments without a prescription
- Permit pharmacists to use greater discretion in partial fills



To watch an explanatory video, visit: http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/rx-safety-alert-system/

Appendix A

Overview of McKesson's Full Set of 2018 Public Policy Recommendations

We recognize some recommendations may require federal or state legislation or regulatory action, and believe such action is warranted. The persistence of this public health crisis calls for more assertive policy interventions. Other recommendations rely on private sector leaders to willingly adopt changes to ensure effective coordination across public and private payers. It is critical we implement solutions that positively affect all patients, regardless of geography or payer coverage, consistently.

Our positions are organized across key stakeholders with the following goals:

Drug Supply
Reduce Supply and Over Prescription

Prescribers
Increase Clinical Knowledge and Patient Engagement

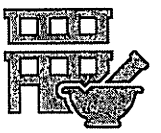
Dispensers
Expand Role of Pharmacists in Care Teams

Patients
Improve Patient Access

Data & Technology
Deploy Solutions to Identify At-Risk Patients

Reduce Supply and Over Prescription

- Encourage FDA to require that manufacturers package opioids in limited dose blister packs to reduce potential for unused product
- Establish programs for the return or destruction of unused opioids to ensure that each patient prescribed an opioid can access drug disposal mechanisms



Drug Supply

We must implement effective strategies to curb overprescribing across the entire healthcare spectrum now, while protecting access for patients with legitimate medical needs for opioid medications.

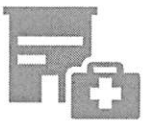
Recommendation: Encourage FDA to require that manufacturers package opioids in limited dose blister packs to reduce potential for unused product. FDA Commissioner Dr. Scott Gottlieb has effectively convened stakeholders and presented thoughtful ways for the Agency to combat opioid abuse. FDA is contemplating a novel idea to leverage blister packs as a way to give providers better options for tailoring how much should be prescribed, relative to the clinical need.[9] For example, according to Dr. Gottlieb: "Suppose the dental community developed an expert guideline that said that no routine dental procedure should require more than a three or five-day initial fill of an immediate-release opioid, and the FDA reviewed and determined that blister packs in these quantities were necessary to ensure safe use. If the drugs were then packaged in blister packs that comported with these durations of use, it could help reduce overall dispensing. More doctors might more readily opt to prescribe these blister packs instead of other treatment options."[10] Dr. Gottlieb states FDA could use any conclusive, significant scientific support for these shorter durations of use as the basis for further regulatory action to drive more appropriate prescribing.

McKesson supports this innovative concept, and recommends that the FDA leverage its current authority to explore optimal packaging approaches. However, we strongly encourage the FDA to work closely with provider specialty societies and guideline developers to ensure that blister packs meet evidence-based guidelines and do not inadvertently encourage overprescribing by limiting prescribers to specific dose ranges.

Recommendation: Establish programs for the return and destruction of unused opioids to ensure that each patient prescribed an opioid can access dispensing drug technology. The Substance Abuse and Mental Health Services Administration (SAMHSA), reports that 50 percent of individuals who misused prescription pain medicines said they obtained them from a friend or relative for free.[11] Patients should not be prescribed excessive amounts of opioids and unused pills should be disposed of promptly and properly. Prescribers must ensure patients understand best practices for storage and disposal to minimize diversion.

McKesson supports public-private partnerships focused on supplying retail pharmacies with drug deactivation bags to be dispensed with an opioid prescription. This recommendation is supported by the President's Commission on Combating Drug Addiction and the Opioid Crisis.[12]

- Incentivize implementation of opioid stewardship or similar clinical excellence programs
- Require all prescribers to participate in approved clinical training and CME as a condition of licensure
- Deploy in-person prescriber training programs to inform better prescribing practices
- Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives, at the time of prescribing and on a consistent basis with clinically-appropriate exceptions



Prescribers

Policymakers should ensure that prescribing clinicians have all information necessary to make fully informed decisions about whether to prescribe an opioid drug. The same is true for patients, who should be advised of risks and benefits by fully trained physicians and other qualified healthcare providers — both consistently and across the care spectrum. Supporting team-based approaches to care delivery will enhance opportunities for collaboration and coordination.

Recommendation: Incentivize implementation of opioid stewardship or similar clinical excellence programs. Stewardship and clinical excellence programs such as the Center for Disease Control and Prevention's (CDC's) Antibiotic Resistance Solutions Initiative have demonstrated success in driving changes to clinical behaviors, enhanced coordination, and improvement in patient outcomes. While components of these programs will vary, they are likely to include enhancing clinical knowledge of comprehensive pain management, multimodal pain management techniques, opioid prescription best practices, consistent communication with patients regarding the risks and benefits of opioid treatment, importance of appropriate disposal of unused drugs, and use of team-based models to support engagement across providers and settings of care. The National Quality Forum's (NQF's) National Quality Partners (NQP) Opioid Stewardship Playbook developed in partnership with CDC and other healthcare stakeholders is an example of how these types of programs may be implemented.

McKesson supports public-private partnerships to incentivize adoption of opioid stewardship and clinical excellence programs. As with any quality improvement effort that seeks to change the way care is delivered, organizational leadership, commitment, and accountability are critical to success. Incentives to implement these programs are critical to drive change across stakeholders – and we specifically encourage communities to reward team-based approaches that bridge the gap between physicians, hospitals, pharmacies and other critical care providers.

Recommendation: Require all prescribers to participate in approved clinical training and CME as condition of licensure. Formal medical education and CME must be improved to better inform clinical practice in pain management. While medical, nursing and pharmacy schools continue to explore avenues to bolster clinical training on comprehensive pain management and opioid use, we recommend that all prescribers participate in approved CME as part of their licensure. It is critical that prescribers have the appropriate clinical knowledge to adhere to best practices in pain management and patient engagement, and not simply focus on reducing opioid use alone. Additionally, a FDA advisory panel has endorsed mandatory training for doctors who prescribe opioids.

McKesson supports policy initiatives that would require all prescribers of opioids to undergo approved clinical training and CME as a condition of licensure. We also continue to support the use of FDA's REMS authority to require mandatory education for healthcare professionals.[13]

Recommendation: Deploy in-person prescriber training programs to reduce overprescribing. In-person provider training is a promising strategy to help ensure that physicians' medical decisions are based on evidence-based information. This approach, which involves one-on-one educational outreach between a specially trained clinician and a physician, has successfully affected the management of health conditions such as chronic obstructive pulmonary disease (COPD) and atrial fibrillation. Recently, the method has been suggested to target physicians who prescribe opioids. Studies in numerous other settings have shown that the strategy has successfully provided physicians with evidence-based information in a way that improves their prescribing practices. A 2017 study concluded that this method of addressing opioid safety and naloxone prescribing was well-received by primary care providers and associated with an increase

of naloxone prescriptions filled by Medi-Cal patients. The approach is also recommended by the NQF Opioid Stewardship Playbook, and is used by the Veterans Health Administration for treatment of opioid abuse disorder.[17]

McKesson supports use of in-person training programs by public and private payers. While current programs may target prescribers viewed to be outliers relative to peers, McKesson believes that these types of education programs should be offered to all prescribers desiring to improve their clinical knowledge and seeking to adopt evidence-based opioid prescribing behaviors. We support public-private partnerships that would enable this one-on-one training across specialties, settings of care and communities.

Recommendation: Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives, at the time of prescribing and on a consistent basis. Consistent messaging and use of shared decision-making tools will help patients understand their pain management options, and risks and benefits of opioid use. These discussions also provide an opportunity to educate patients on the safe storage and disposal of unused opioids. Patients should also be informed that under the Comprehensive Addiction and Recovery Act (CARA) rules, they may request partial fills of their prescriptions. Allowing patients to request partial fills helps to reduce the risk of "extra" pills being improperly disposed, lost, stolen, sold or given to others. Patients determined "at risk" by clinical guidelines should undergo consultation, attestation and/or confirmation testing for subsequent fills of prescription opioids.

McKesson strongly supports policy initiatives to ensure that patients receive this critical education for new and subsequent prescriptions to ensure they are consistently informed of the clinical options and risks of continued opioid use. We support public-private partnerships that ensure this education occurs as part of routine clinician visits, or as part of opioid stewardship programs as recommended by the National Quality Forum's Opioid Stewardship Playbook. [18]

- Pilot pharmacist-led opioid care management models
- Allow pharmacists to participate in and be reimbursed for SBIRT activities
- Expand access to MAT by allowing pharmacists to provide and be reimbursed for MAT
- Increase access to opioid overdose antidotes, such as naloxone, by allowing pharmacists to dispense and be reimbursed for such treatments without a prescription
- Permit pharmacists to use greater discretion in dispensing partial fills
- Train pharmacists on best practices to evaluate legitimacy of opioid prescriptions

Dispensers

As examples below highlight, states are beginning to recognize and empower pharmacists to do more to combat the opioid crisis. We recommend the following actions to ensure that pharmacists within their scope of licensure are leveraged, trained, and reimbursed for preventing, identifying, and treating opioid abuse disorder (OUD) and other substance use disorders (SUDs).

Recommendation: Pilot pharmacist-led opioid care management models. Pharmacists are uniquely positioned to have a comprehensive view of a patient's health status, since they see the prescriptions and diagnoses of multiple physicians and generally have strong relationships with their patients. This vantage point allows pharmacists to detect potential problems of non-adherence, drug interactions with opioids, and potential misuse and/or signs of potential abuse. Additionally, with proper medication adherence increasingly linked to better clinical outcomes and lower healthcare costs, pharmacist-led medication therapy management (MTM) is increasingly being employed by federally qualified health centers (FQHCs) and other care settings.

HHS' Indian Health Service (IHS) offers a noteworthy example of effective employment of pharmacists to provide the clinical expertise and critical leadership support needed to implement a comprehensive approach to opioid safety throughout Indian Country. Clinical pharmacists serving patients at IHS locations in the Southwest, Midwest, and Great Lakes regions have "transcended traditional dispensing roles by augmenting services in the management of primary care patients with pain and opioid use disorders. Novel approaches include patient consultation and education from within the pharmacy, patient management in

chronic non-cancer pain clinics, and care coordination through MAT programs. Pharmacists in some facilities are fully integrated into multidisciplinary chronic pain management programs and deliver care through a patient-centered model. Clinical roles range from individual consultation appointments to full prescriptive authority for controlled substances."[19]

We recommend public and private payers, including the Center for Medicare & Medicaid Innovation (CMS Innovation Center), test pharmacist-led care delivery models, with specific focus on opioid care management. Lack of Medicare recognition and inconsistent payer reimbursement often limit the formal roles pharmacists play in alternative payment models. Pharmacists' clinical training, unique vantage point, and frequency of patient touch points provide a unique opportunity for these experts to engage on the frontlines of the opioid epidemic.

We encourage payers and providers to consider a robust team-based approach where the pharmacist is positioned as the pharmacologic leader and coordinator across the care continuum. Services they may provide include: assessing clinically appropriate drug doses, identifying potential drug-drug interactions, educating patients on risks and benefits of treatments, assessing patient risk of misuse and abuse, evaluating pain status and need for ongoing or alternative therapy, and educate on appropriate drug storage and disposal techniques. Pharmacists are also well positioned to assess whether certain high-risk patients would benefit from being co-prescribed opioid reversal agents such as naloxone. It is critical that we leverage all members of the healthcare ecosystem and drive team-based approaches to ending the opioid epidemic.

Recommendation: Allow pharmacists to participate in and be reimbursed for SBIRT activities. Pharmacists should be permitted to provide and be reimbursed for SBIRT activities, which help to identify individuals who may struggle with alcohol and/or substance use. The program includes a screening and, if needed, a brief intervention to educate individuals about their use, alert them to possible consequences, and motivate them to take steps to change their behavior. Virginia is currently the only state that empowers and reimburses pharmacies to provide SBIRT services under Virginia's Addiction Recovery Treatment Services ("ARTS") benefit for Medicaid patients.[20]

McKesson joins the National Community Pharmacists Association (NCPA) in encouraging other states to follow Virginia's example in permitting pharmacists to provide and be reimbursed for SBIRT services.[21]

Recommendation: Expand access to MAT by allowing pharmacists to provide and be reimbursed for MAT. Addiction experts consider MAT, which combines medications and behavioral therapy, as the gold standard in addiction care. Therefore, as addiction experts contend, policymakers should elevate expanded access to FDA-approved MAT as a critical component of fighting the opioid crisis. We applaud HHS Secretary Alex Azar's acknowledgement that "the evidence on [MAT] is voluminous and ever-growing."[22] The President has proposed to "test and expand nationwide [for Medicare] a bundled payment for community-based medication-assisted treatment, including Medicare reimbursement for methadone treatment for the first time."

We support this and other proposals to expand community-based MAT, particularly in rural areas. However, we strongly urge that pharmacists be considered eligible to provide and be reimbursed for MAT services in any nationwide pilot and expansion.

Today, nearly every state permits pharmacists to forge collaborative practice agreements (CPAs) with physicians and other prescribers to provide advanced care to patients, including components of MAT, and some states allow pharmacists to prescribe Schedule II-V controlled substances under a CPA.[23] States that allow such agreements have found that pharmacist involvement in MAT helps to increase access, improve health outcomes, and reduce the risk of relapse.[24] However, pharmacists in states that allow them to prescribe Schedule III controlled substances, such as MAT medications, are still prohibited from doing so. This is because under federal law, pharmacists are ineligible for Drug Addiction Treatment Act (DATA) waivers that are available for other mid-level practitioners, such as physician assistants (PAs) and nurse practitioners (NPs).

McKesson urges Congress to pass the Expanded Access to Opioid Abuse Treatment Act of 2017 (H.R. 3991), which would enable pharmacists to obtain DATA waivers and expanded access to MAT in states where they are permitted to do so.

Recommendation: Increase access to opioid overdose antidotes, such as naloxone, by allowing pharmacists to dispense and be reimbursed for such treatments without a prescription. Naloxone – also known as Narcan – is deemed by FDA to be a safe and effective antidote to opioid overdoses and is currently available without a written prescription in most states. While such antidotes should not be considered a long-term solution, the reversal agent

can mean the difference between life and death for individuals.

McKesson believes pharmacists in every state should be permitted to dispense and be reimbursed for opioid overdose antidotes without a prescription. As a matter of good clinical practice and care coordination, the pharmacist would be expected to communicate this care decision to the appropriate prescribing provider(s).

Recommendation: Permit pharmacists to use greater discretion in partial fills. According to a Johns Hopkins Bloomberg School of Public Health study, six out of 10 adults prescribed opioid painkillers have leftover pills,[25] which poses significant risk of misuse and diversion. Pharmacists should be empowered to exercise their clinical judgment to be able to reduce the number of unused opioid pills. CARA permits a prescription for a Schedule II controlled substance to be partially filled if: (1) it is not prohibited by state law; (2) the partial fill is requested by the patient or the prescriber (note: not pharmacist); and (3) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.[26] To date, only a handful of states allow pharmacists to partially fill a prescription under current CARA rules.

McKesson supports changes to CARA that would allow pharmacists to exercise their professional judgment in deciding to partially fill prescriptions. We also encourage Drug Enforcement Administration to clarify that pharmacies may dispense less than prescribed amounts of opioids in response to any health plan designs that would limit coverage of opioids.

Recommendation: Train pharmacists on best practices to evaluate legitimacy of opioid prescriptions. Pharmacists receive rigorous clinical training and have strong relationships with their patients. They represent a critical line of defense and should be adequately equipped to help prevent opioid abuse, misuse, and diversion.

We support pending legislation in Congress that would provide for the development and dissemination of programs and materials for pharmacists and other providers to facilitate detection of fraudulent prescriptions and other behavior linked to abuse and diversion.

- Require co-prescribing of overdose reversal agents for high-risk patients
- Promote community-based pilot programs focused on veterans
- Pilot recovery coach programs

Patients

Meaningful solutions must have better health for patients as the highest priority. The right solutions will include effective patient safety measures while ensuring access to care for patients in need. McKesson encourages lawmakers to ensure that proper safeguards are in place to make certain that patients with a legitimate medical need do not experience disruptions in their ability to access needed pain medications. It is important that every opioid management program and policy have proper exemptions in place for cancer patients and terminally-ill patients, since it is estimated that pain occurs in up to 70 percent of patients with advanced cancer.[27] In addition, all individuals battling with addiction, regardless of how they got there, should receive the same standard of care that any other patient battling any other disease would receive.

Recommendation: Require co-prescribing of overdose reversal agents for patients who are considered high-risk and for patients with high-dose prescriptions of opioids. In 2017, the American Medical Association (AMA) Opioid Task Force issued guidance encouraging physicians to consider co-prescribing naloxone with prescription opioids when clinically appropriate for patients who are at risk for opioid overdose or might be in a position to help someone else at risk.[28] The guidance includes several questions that physicians should consider to determine whether they should co-prescribe naloxone to a patient, a family member, or close friend of the patient. Furthermore, the Johns Hopkins Bloomberg School of Public Health also recommends that patients on a high-dose opioid carry naloxone, just as individuals with peanut allergies carry an EpiPen in case they accidentally ingest a peanut product.[29]

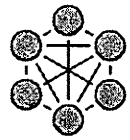
McKesson supports policies that would require health plans to cover naloxone when prescribed by a physician or other qualified healthcare provider for clinically appropriate patients. Additionally, we believe that pharmacists in all states should be able to dispense naloxone for clinically appropriate patients without a prescription. As a matter of good clinical practice and care coordination, the pharmacist would be expected to communicate this care decision to the appropriate prescribing provider.

Recommendation: Promote community-based pilot programs focused on prevention and care for veterans. The Department of Veterans Affairs (VA) has reported that veterans are twice as likely as non-veterans to die from overdose of addictive pain medicines, reflecting the high levels of chronic pain among the veteran population, particularly those who served in Iraq and Afghanistan.[30] We applaud VA efforts to combat overprescribing, including the Department's recent initiative to publicize information on opioids dispensed from VA pharmacies[31] and its commitment to implement academic detailing programs focused on overdose education, naloxone distribution, and opioid use disorder.[32]

McKesson encourages the development of community-based pilot programs focused on preventing opioid abuse and misuse among veterans, including those that draw on VA-tested best practices.

Recommendation: Pilot recovery coach programs to help patients. Recovery coach programs are currently being piloted in eleven emergency departments across Massachusetts.[33] Governor Charlie Baker recently filed legislation to create a commission to review and make recommendations regarding the credentialing and registration standards that should govern recovery coaches.[34] Under a pharmacist-led care management model, pharmacists could also be trained to provide counseling and recovery coaching services whenever patients have difficulty in accessing substance-abuse clinicians due to the increasing number leaving the profession.

We are encouraged by these programs and support policies that would drive the development of national recovery coach models. We encourage public and private payers to cover these services today when provided by qualified healthcare providers, such as pharmacists.



Data & Technology

- Implement a national prescription safety-alert system for both dispensers and ultimately prescribers
- Require use of electronic prior authorization (ePA)
- Ensure PDMP interoperability by 2020 and compatible safety alert systems that will increase utilization and provision of real time and actionable data for clinical decision making at the point of prescribing and dispensing
- Require DEA to provide more data to registrants who report to the Automation of Reports and Consolidated Orders System (ARCOS) database
- Encourage wholesale distributors to provide states with the same ARCOS and suspicious order monitoring (SOM) data submitted to DEA
- Harmonize controlled substances sales reporting system

The U.S. is the global leader in technological innovation. But when it comes to harnessing technology to address the worst public health crisis in modern history, our country has failed to mobilize its full potential. This is unacceptable for patients and for the healthcare professionals who are on the front lines caring for patients. Physicians, pharmacists, and clinicians agree that the realities of delivering care today – patient demands and tightening reimbursement – require 21st century technology that is interoperable, real time and easily accessible, in workflow. We recommend the following policy recommendations and private sector-led solutions to protect against abuse and to equip doctors, pharmacists, public health officials, and others with the tools necessary to help end the opioid crisis.

Recommendation: Implement a nationwide prescription safety-alert system that would provide pharmacists, and ultimately prescribers with real-time alerts to identify patients who are at risk for opioid overuse, abuse, addiction or misuse. We strongly support the implementation of a nationwide prescription safety-alert system, a model conceived by the National Council for Prescription Drug Programs (NCPDP) and recently cited by the Duke Margolis Center for Health Policy.[35] The prescription safety-alert system would use patient prescription history data and clinical rules to identify patients and prescription patterns that may indicate risks of opioid overuse, abuse, addiction or misuse. Pharmacies would receive real-time in workflow alerts indicating

that the pharmacist should gather additional patient information before dispensing. This might include a more in-depth conversation with the patient, a consultation with the prescribing physician(s), and review of the relevant state PDMP data. To maximize success, the prescription safety-alert system must have access to data from all entities dispensing covered controlled substances.

McKesson urges HHS/FDA, through its existing REMS authority to require that manufacturers only provide covered controlled substances to pharmacies and healthcare providers that participate in a prescription safety-alert system.

Recommendation: Harness ePA to prevent misuse and accelerate access for patients with legitimate need. Employers and payers have implemented programs to detect and intervene in inappropriate prescribing of opioids. PA, a process to verify that medications or procedures are medically necessary, is used by payers before they grant coverage approvals.[36] A study of Medicaid patients in Pennsylvania found that enrollees within plans that subject opioids to PA policies had lower rates of abuse and overdose after initiating opioid medication treatment[37] While the use of PA is frequently associated with reductions in use of opioids, traditional PA – most often completed via handwritten faxed forms or phone calls – can frequently place significant burdens on physicians, pharmacists, and patients who legitimately need prescription painkillers to manage their conditions.

A 2016 AMA survey reported that 75 percent of respondents said handling PA requests were a "high" or "extremely high" burden and that an average of 16.4 hours of physician and staff time each week was spent on completing PA requirements to get patients the medicines and procedures they needed.[38] Pharmacists also reported similar challenges. According to the ePA National Adoption Scorecard, 66 percent of prescriptions rejected at the pharmacy require PA and 36 percent of those prescriptions are abandoned.[39] Clinicians, including pain experts, report that patients with legitimate need for pain medications are increasingly, involuntarily losing access to the medicines they need due partially to rigid and needlessly cumbersome efforts to prevent overprescribing. Prior authorization and other interventions meant to combat overprescribing must be improved by harnessing technology. ePA is a proven and promising solution that helps physicians and pharmacists securely and electronically transmit PA requests within their clinical workflows up to three times faster than paper-based PA and with fewer mistakes.

McKesson supports policy initiatives that would enhance the use of ePA across all payers. We support current federal legislation that would mandate use of ePA in Medicare Part D and strongly urge commercial payers to adopt similar policies. Additionally, we support state legislative efforts to standardize the PA process for drugs and services. It is critical we reduce access hurdles for patients and minimize administrative burden on our already strained healthcare ecosystem.

Recommendation: Require eRx of all controlled substances. Handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to prescription opioids.[40] eRx allows prescriptions to be transmitted to pharmacies securely without risk of alteration or diversion. E-prescribing of controlled substances (EPCS) is currently permitted in all 50 states, yet is only required in a handful of states. Research on EPCS has been scarce, but surveys have shown that prescribers are generally optimistic about the benefits of EPCS.[41]

We join the National Association of Chain Drug Stores (NACDS) and others in support of efforts by Congress to require e-prescribing of opioids in Medicare Part D, and encourage other payers to adopt similar policies. We strongly believe that all opioids in this country should be prescribed electronically.

Recommendation: Require DEA to provide more data to registrants who report to the ARCOS database. The Controlled Substances Act requires wholesale distributors and other DEA registrants to report certain transaction data to DEA, which is housed in a database known as ARCOS. This data shows how many pills were sold, where in the U.S. they were sent, and what pharmacies bought them.

McKesson supports pending legislation that would require DEA to provide registrants who report to the ARCOS database with information regarding (1) total number of specific distributors serving a specific pharmacy for reportable drugs (aggregated by the name and address of each pharmacy) and (2) the total number and type of opioids distributed to each pharmacy in order to help distributors further assess product orders or provide other supportive information.

Recommendation: Encourage wholesale distributors to provide states with the same ARCOS and SOM data submitted to DEA. States may not have access to the ARCOS data, as well as reports of suspicious orders – requests from customers that are unusual in size, deviate substantially from normal patterns, and unusually frequent.

McKesson is committed to voluntarily providing ARCOS and SOM data to any state that requests the information.

Recommendation: Harmonize controlled substances sales reporting systems. McKesson is committed to working with governors, attorneys general, the National Association of Boards of Pharmacy (NABP), and DEA to harmonize controlled substances sales reporting systems. Such a policy would be in a form and frequency conducive to rigorous and timely analysis, would facilitate data sharing between state and federal governments, and would ultimately help to better identify and prevent non-medical use of prescription drugs.

McKesson supports state efforts to adopt a uniform system for suspicious order reporting, so that states can receive standardized reports of suspicious orders in a timely and consistent manner.

Conclusion

Our country has made some progress in prioritizing and combating the opioid epidemic, but more must be done. Until we implement innovative solutions, like the ones we've recommended, we fear that the opioid crisis will persist. Meaningful solutions require doctors, pharmacists, distributors, manufacturers, payers, policymakers, and regulators, to come together. McKesson is committed to partnering with the Administration, Congress, the states, and all stakeholders who share our dedication to working together, with urgency, to help to end this national crisis. As never before, we must look to private sector innovation to inform and power public and regulatory policies that will break through the barriers that have stymied meaningful and sustainable barriers to addressing the public health crisis of our day. If you'd like partner with us on these solutions or would like more information, contact McKesson Public Affairs at PublicAffairs@McKesson.com.

Appendix B

Summary of McKesson 2017 – 2018 Public Policy Recommendations

Drug Supply

We continue to support our 2017 recommendations and new emergent public and regulatory policies that encourage policymakers to look "upstream" in the supply chain to prevent abuse, misuse and diversion: **(1) Enact nationwide opioid prescription limits (7-day supply limit for acute pain), (2) Permit partial fills, and (3) Require DEA to revisit annual production quotas.**

Additionally, we call for expanded reforms to better manage supply of drugs in our communities and facilitate the proper disposal of unused opioids.

- **Encourage FDA to consider limited dose blister packs**
- **Establish programs for the return and destruction of unused opioids**

Prescribers

We continue to support our 2017 recommendation that the **FDA harness the power of its REMS programs**, particularly as it relates to prescriber education and training.

Appropriate opioid prescribing is built upon comprehensive pain management knowledge, understanding of opioid prescribing guidelines, and effective patient engagement. As such, we recommend immediate reforms to ensure prescribers adopt evidence-based strategies today.

- **Incentivize implementation of opioid stewardship or similar clinical excellence programs**
- **Require all prescribers to participate in approved clinical training and CME as a condition of licensure**
- **Deploy in-person provider training programs by independent medical experts**
- **Ensure all patients receive education on risks and benefits of opioids and clinically appropriate treatment alternatives consistently**

Dispensers

We continue to support our 2017 recommendation **requiring opioid management programs for all payers and providers.**

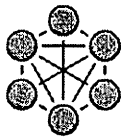
However, this year we are also focused on ensuring that pharmacists practicing within the scope of their licensure are leveraged, trained, and reimbursed for preventing, identifying and treating opioid abuse disorder and other substance abuse disorders.

- **Pilot pharmacist-led opioid care management models**
- **Recognize and reimburse pharmacists for Screening, Brief, Intervention and Referral to Treatment (SBIRT) and MAT, and opioid overdose antidotes**
- **Permit pharmacists to use greater discretion in partial fills**
- **Train pharmacists on best practices to evaluate legitimacy of opioid prescriptions**

Patients

While our policy recommendations for prescribers and dispensers also seek to improve patient engagement and expand access to treatments such as SBIRT and MAT, we also recommend:

- **Require co-prescribing of overdose reversal agents for high-risk patients**
- **Promote community-based pilot programs focused on veterans**
- **Pilot recovery coach programs**



Data & Technology

We continue to support our 2017 recommendations that leverage data and technology to improve the flow of prescription data and ensure clinicians and pharmacies have the necessary clinical data prior to prescribing and dispensing opioids: **(1) Integrate a national prescription safety system into the pharmacy dispensing process, (2) Require eRx for all controlled substances nationally, and (3) Promote utilization of and improve information sharing among PDMP and data integration into a patient's electronic health record.**

This year we build upon these recommendations and seek to increase data sharing across stakeholders.

- **Implement the NCPDP national prescription safety-alert system concept for dispensers, and ultimately prescribers**
- **Require use of electronic prior authorization (ePA)**
- **Require DEA to provide more data to registrants who report to the ARCOS database**
- **Encourage wholesale distributors to provide states with the same ARCOS and SOM data submitted to DEA**
- **Harmonize controlled substances sales reporting systems**

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