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

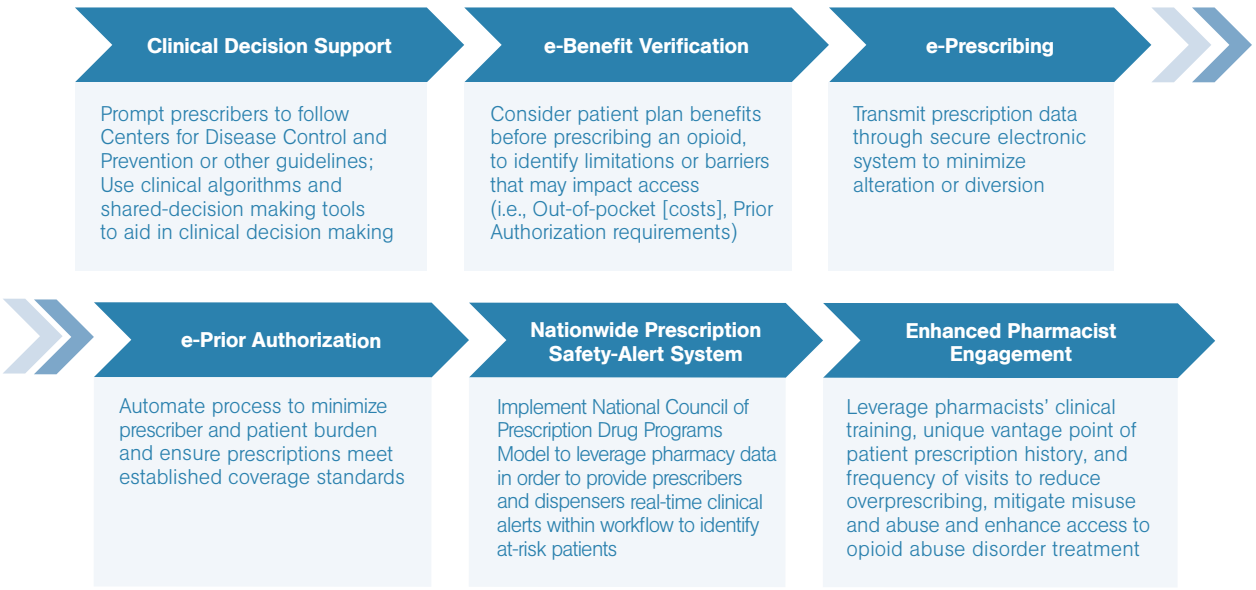
It is critical that we drive a culture of change that embraces a team-based approach to comprehensive pain management. This requires coordination across all stakeholders that impact the supply chain and those on the front lines of care delivery. Data and technology solutions must be thoughtfully deployed 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:

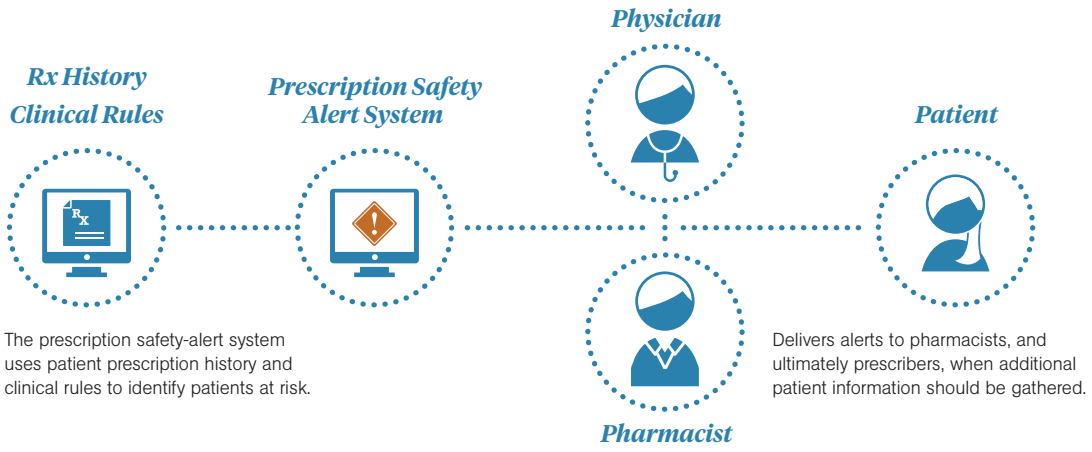
- Health and Human Services/Food and Drug Administration, through its existing Risk Evaluation and Mitigation Strategy authority, should require that manufacturers only provide covered controlled substances to pharmacies and healthcare providers that participate in a prescription safety-alert system

### *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



***Drug Supply***

- 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

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]



***Prescribers***

- 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

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]




***Dispensers***

- 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

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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