The Effective Medicaid Pharmacy Program

A White Paper for Medicaid Directors and State Agency Personnel

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About Us

New England States Consortium Systems Organization

The New England States Consortium Systems Organization (NESCSO) is a non-profit corporation governed by the New England State Health and Human Service agencies and the University of Massachusetts Medical School. NESCSO supports the New England State Health and Human Service agencies through the pursuit of initiatives that promote the:

- continuous development of State employees through training and resources needed to meet the challenges of their jobs;
- effective and efficient procurement and application of information technology;
- attainment of cost-savings and other efficiencies through multi-state procurement of goods and services.

NESCSO supports the nation’s health and human service agencies through hosting the annual Medicaid Enterprise Systems Conference. The Conference brings together thought leaders from the public and private sectors to share knowledge and ideas related to Medicaid Enterprise systems and initiatives. The goal of these regional and national efforts is to improve the effectiveness and operations of Health and Human Service agencies so that they are better able to meet the needs of the people they serve.

Commonwealth Medicine, University of Massachusetts Medical School

Commonwealth Medicine’s primary focus is to help Medicaid and other human service agencies accomplish their missions. As the health care consulting and operations division of UMass Medical School, it draws on the academic knowledge and public health service expertise of Massachusetts’s only public medical school to provide comprehensive, innovative health care and policy solutions. With Commonwealth Medicine’s help, government agencies, nonprofits, and managed care organizations are able to meet today’s health care challenges — and are prepared for what’s to come.

Offering expertise that has touchpoints across health and human services, the organization’s comprehensive suite of solutions supports program integrity, improves member health, enhances public programs, and fosters a high-quality delivery system.

NESCSO Pharmacy Learning Community

The NESCSO Pharmacy Learning Community is comprised of representatives from the six New England Health and Human Services agencies engaged in program and financial policies related to Medicaid-funded pharmacy services. The Pharmacy Learning Community meets throughout the year to address topics of common interest, including value-based contracting, cell and gene therapy, and drug prices. The NESCSO Pharmacy Learning Community also collaborates on projects such as a regional cost of dispensing survey and an Agency for Healthcare Research and Quality funded study to evaluate the uptake of new hepatitis C virus medications among New England Medicaid members.
Introduction

The purpose of this white paper is to provide Medicaid Directors and State Agency personnel who are new to Medicaid with guidance on the components of an effective Medicaid pharmacy program. We define such a program as one that provides Medicaid members with access to medically necessary medications, that are:

1. cost-effective,
2. aligned with best clinical practice, and
3. provided in a transparent environment (clinical, governance, price).

We performed an environmental scan supplemented by key informant interviews to identify best practices and emerging opportunities for Medicaid pharmacy programs.

The ability of a Medicaid pharmacy program to achieve these goals is impacted by its administrative structure; the pharmacy benefit delivery system (state-run or delegated to Medicaid managed care organizations [MCO]); and the influence of external factors (such as legislation or the pharmaceutical pipeline). Levers available to help states achieve program goals include drug rebates, quality and performance measurement, preferred drug lists, drug utilization review, utilization management, prior authorization, and novel payment methodologies.

Administrative Structure

Medicaid Directors have a variety of options regarding where a pharmacy program fits within the structure of the overall organization. Pharmacy can be a stand-alone unit or part of the Medical or Clinical Services groups. Because pharmacy is a major component of state health care spending as well as a generator of significant rebate offsets, some key informants felt very strongly that the pharmacy program should be independent of the medical program. This model provides the pharmacy program with a direct relationship to senior leadership and elevates the importance of the pharmacy benefit as a strategic policy and financing tool.

Conversely, we also heard the argument for an administrative structure that explicitly combines the pharmacy and medical programs. In this model, emphasis is placed on integrating the management of medical care and services with the pharmacy benefit drugs. This is a particularly important structure as specialty drugs gain more market share, many of which are physician-administered drugs (PADs) provided in office or hospital outpatient settings. There are significant opportunities to manage PADs as well as the site of service. Furthermore, spending on the pharmacy side that may achieve savings on the medical side can be measured and monitored with integration across the two programs.

The main take-away is that the pharmacy program should not be viewed simply as a transactional program: one that pays claims. This approach overlooks a powerful tool to impact the health of Medicaid members and ignores the increasing role pharmaceuticals have in Medicaid program costs.
In-house pharmacy team

The person in charge of the pharmacy program should have a strategic understanding of the broad dimensions of Medicaid pharmacy and be able to make sense of complex issues and an uncertain future.1 Several key informants felt strongly that the pharmacy program lead should be a pharmacist. As subject matter experts, pharmacists are uniquely positioned to provide strategic insights into the rapidly evolving medication and health care delivery landscape. However, effective Medicaid pharmacy program leads are not always pharmacists and can still successfully achieve programmatic goals, especially when supported by a strong in-house clinical pharmacy team. In either case, the pharmacy program lead should be able to readily tap into a network of pharmacist and other professional organizations. There are a number of national organizations that support Medicaid pharmacy through thought leadership, networking, and policy and legislative technical assistance, among other activities (see Appendix A).

In an ideal world, the Medicaid pharmacy team would include a range of expertise. Personnel to consider for the pharmacy team include data and business analysts, policy analysts, pharmacoeconomics experts, project managers, and auditors. Furthermore, to keep up with the rapid evolution of medication therapies and innovative contracting approaches, the pharmacy program would benefit from direct access to actuaries as well as legal and contracting resources with knowledge of the issues related to the Medicaid pharmacy benefit and the pharmaceutical industry. It is also important that Medicaid programs address retention of their skilled staff, which may be accomplished through professional development opportunities, attendance at national conferences, and defined career ladders.

We understand that it is unrealistic that most Medicaid programs would be able to access all these resources as direct staff. This knowledge and expertise can be accessed through partnerships with universities and other organizations. For example, for clinical, research, and policy support, Massachusetts Medicaid partners with Commonwealth Medicine (University of Massachusetts Medical School) and Oklahoma Medicaid with Pharmacy Management Consultants (University of Oklahoma College of Pharmacy).

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Outsourcing

The decision to outsource pharmacy benefit management and other program functions is based on the Medicaid program structure and business needs (see Box 1).²⁻⁴ Examples of functions that may be outsourced to vendors include claims processing, rebate management, formulary/preferred drug list management, prior authorization services, retrospective drug utilization review (DUR), and DUR board and pharmacy and therapeutics committee management. Our key informants emphasized the importance of collaboration between the in-house pharmacy team and vendors. To varying degrees, the key informants we interviewed leverage external resources and vendor partners to provide key services, supplement internal projects, or provide additional expertise. All key informants reported having data analysts on staff, whether they are part of the pharmacy program or larger Medicaid program, but emphasize the importance of supplementing their internal data analytic capabilities with external analyses and expertise.

Delivery Systems

Important considerations for pharmacy benefit programs managed by MCOs

State Medicaid agencies need to consider whether they will utilize MCOs to manage some or all of the Medicaid benefit. Part of this decision is whether or how much of the pharmacy benefit should be included in the MCO contract. If certain drug classes are carved-out of the MCO contract, or if the pharmacy benefit is carved-out entirely, the Medicaid program will have more direct control and oversight of the pharmacy spend. Conversely, MCOs may face greater challenges providing a comprehensive benefit for

BOX 1.
Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) act on behalf of payers to negotiate rebates, process prescription claims, and manage drug formularies. PBMs manage pharmacy benefits for 270 million Americans, with three PBMs handling 70-75% of all prescription claims.² PBMs may be standalone (e.g., MagellanRx, Change Healthcare) or vertically integrated with a health plan (e.g., UnitedHealth Group and OptumRx, Aetna and CVS, and Humana and Express Scripts). While vertical integration may offer members better access to coordinated care, key informants highlighted the need for vigilant monitoring as there are concerns that these arrangements are associated with increased spending and the potential for reduced transparency.³

Spread pricing is a major issue currently being addressed by Medicaid programs. This is a practice by which PBMs charge payers more than they pay the dispensing pharmacy. Due to this issue, several states are changing their relationships with PBMs, either through legislative (e.g., prohibition of spread pricing) or administrative (e.g., demanding contract transparency or ending contracts and designating a state agency to act as PBM) approaches.⁴

Medicaid members if they are not able to oversee all aspects of health care delivery. In another scenario, the Medicaid program may decide to include pharmacy in the MCO contract but designate classes for which the State wants to negotiate rebates and establish the formulary.

For states that deliver the pharmacy benefit through a Medicaid MCO, the primary consideration raised by key informants was the challenge of rigorous oversight. A theme that arose consistently was the need for trust between the Medicaid program and their partner MCOs and PBMs. Furthermore, Medicaid programs should ensure transparency in reporting and data analysis. Appropriate oversight can be accomplished through supportive and transparent contract language, structured evaluation tools, and an adequately resourced oversight staff at both the pharmacy and Medicaid program levels.

**Role of the pharmacist**

In addition to their role in the medication distribution process, pharmacists contribute to patient care through the provision of enhanced pharmacy services. These include assessment of the appropriateness and effectiveness of medication regimens, education of patients and health care professionals, and direct support to patients through a number of medication management services such as adherence services, medication therapy management, medication administration, and point of care medical testing. While some Medicaid programs have pursued strategies to improve member outcomes by reimbursing pharmacists for these enhanced pharmacy services, it is generally agreed that pharmacists are underutilized. The primary barrier to widespread incorporation of expanded pharmacist roles in the health care delivery system has been the lack of recognition of pharmacists as providers in national health legislation and policy with commensurate compensation for recognized services. We encourage State Medicaid programs to consider the role pharmacists can play to improve member outcomes.

**External Factors**

The complex and evolving nature of medication therapy and health care delivery has fundamentally altered Medicaid pharmacy program efforts over time. In the past, Medicaid programs primarily focused on managing utilization of frequently-prescribed, high-cost medications by designating preferred products and shifting utilization from brand to generic medications. While these activities still play an important role in the modern Medicaid pharmacy program, efforts have necessarily expanded over time to accommodate a rapidly changing pharmaceutical and policy landscape. Due to rebates and the increasing price of generic medications, the utilization management strategy has shifted from being primarily a ‘generics first’ approach to a ‘lowest net cost’ approach. Specialty medications have created additional challenges for Medicaid programs; in FY 2017, they represented just 1.2% of Medicaid claims in FY 2017, but accounted for nearly 44% of spending.

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Legislation and policy

Federal legislation including Medicare Part D, the Affordable Care Act, and the 340B Program have significantly impacted utilization and cost for Medicaid pharmacy programs. Currently, there are several proposals under consideration at state and federal levels that could directly or indirectly alter how Medicaid programs pay for medications. These proposals include the elimination of safe harbors for rebates, drug price transparency efforts, removal of barriers to generic and biosimilar market entry, and tying certain drug prices to an international reference price. Regarding the 340B Program, states must have a process in place to prevent duplicate 340B and rebate discounts across both fee-for-service and Medicaid managed care programs.

Pharmaceutical pipeline and drug discovery

Scientific breakthroughs, advances in clinical trial design, and evolution of the Food and Drug Administration’s regulatory approach will continue to advance the paradigm of drug discovery and development. We have already seen the number of drug approvals increase over recent years, with many medications entering the market with outcomes and prices unlike those seen previously. This includes specialty medications (notably for the treatment of oncology and inflammatory disorders) and cell and gene therapies, many of which have significantly improved clinical outcomes and even have brought cures to patients. We are starting to see applications of precision medicine and how artificial intelligence and digital technology will transform how we discover and deliver therapies. Thus, Medicaid programs are increasingly challenged to ensure access to medication that is cost-effective and aligned with best clinical practice. This balancing act will continue to be a prominent feature of Medicaid pharmacy programs as, thankfully, scientific progress shows no signs of slowing.

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8 On January 31, 2019, the U.S. Department of Health & Human Services (“HHS”) issued a proposed rule which seeks to modify the discount safe harbor under the federal Anti-Kickback Statute to eliminate protection for certain drug discounts paid by manufacturers to Medicare Part D Plans, Medicaid MCOs, or their PBMs. Available at: https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf. [Accessed: May 23, 2019].


10 On May 10, 2019, the U.S. Department of Health & Human Services (“HHS”) issued a final rule which requires direct-to-consumer television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost. Available at: https://www.govinfo.gov/content/pkg/FR-2019-05-10/pdf/2019-09655.pdf. [Accessed: May 22, 2019].

11 On May 9, 2019, the Food and Drug Administration issued a guidance document intended to assist sponsors in demonstrating that a proposed therapeutic protein product is interchangeable with a reference product. Available at: https://www.fda.gov/media/124907/download. [Accessed: May 23, 2019].


State Levers

State Medicaid pharmacy programs have several levers available to them to respond to these external factors.

Drug Rebates (see Box 2\textsuperscript{17}): Key informants placed great emphasis on the importance of a strong rebate program. This involves having a trusted vendor and/or in-house capabilities as well as an innovative approach to contracting. One key informant mentioned that although their rebate vendor demonstrates good performance for rebate negotiations, their experience suggests that rebate invoicing should be managed in-house to ensure the greatest returns.

Quality and Performance Measurement: Medicaid programs should consider defining standardized measures to provide strategic insights and benchmarking both within and across programs and time. Many fiscal (e.g., per-member-per-month medication expenditures, total cost of care, and rebate dollars received) and quality measures (e.g., CMS Adult and Pediatric Health Care Quality Measures) are routine. Other measures may include patient satisfaction as well as public and stakeholder feedback.

Preferred Drug List (PDL): The PDL is an important tool for supplemental rebate negotiations and has traditionally been applied to drugs that have therapeutically equivalent alternatives. Placement of drugs on the PDL can be used to drive increased market share. As more novel, first-in-class drugs enter the market without therapeutically equivalent alternatives, other strategies will need to be considered by Medicaid programs or multi-state purchasing consortia when negotiating supplemental rebate agreements.

Drug Utilization Review (DUR), Utilization Management (UM) and Prior Authorization (PA): DUR is a foundational component of the Medicaid pharmacy program. DUR is implemented through retrospective and prospective activities with the purpose of ensuring safe and effective use of prescription medications. DUR Boards provide oversight of the criteria and standards that guide prospective and retrospective drug review in the Medicaid program. Their activities and member constitution vary from state to state. It is important for states to actively manage the potential impact of conflicts of interest for members serving on DUR Boards.

UM includes strategies such as quantity limits, step therapy, and days’ supply requirements (for example, 90-day supplies for selected medications or medication classes).

PA ensures that the use of certain high-cost and/or high-risk medications is medically appropriate and in alignment with the program’s PDL. A robust PA program will have both a positive clinical and economic impact. For example, the Massachusetts Medicaid program’s experience with hepatitis C virus (HCV) medications demonstrates high HCV cure rates and a 10:1 return on investment for clinical program management. \(^{18,19}\)

**Novel Payment Methodologies:** States are employing novel payment methodologies as an additional lever to reduce pharmacy spend and ensure member access to necessary treatments. Two prominent examples include value-based outcomes arrangements and subscription payment models. Furthermore, some state Medicaid programs are incorporating pharmacy into alternative payment models either by including pharmacy in total cost of care for managed care or accountable care models or designing value-based reimbursement strategies (e.g., pay for performance or capitated payment models) for enhanced pharmacy services. \(^{20,21}\)

**Conclusion**

The future of medication therapy for patients is hopeful and exciting. State Medicaid programs can ensure they realize the value of the pharmacy benefit by committing enough resources to management and oversight, maintaining awareness of the influence of external factors, and strategically leveraging existing tools and resources. With the medication and health care delivery landscapes continuing to evolve rapidly, Medicaid programs remain uniquely positioned to employ innovative strategies to further control drug spend and ensure access to necessary medications — for all members.


Appendix A.
Selection of Organizations that Support Medicaid and Medicaid Pharmacy

Academy of Managed Care Pharmacy (www.amcp.org)
Professional organization dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring wise use of health care dollars.

- Hosts two annual meetings (spring and fall) and webinars throughout the year
- Publishes a peer-reviewed journal, the Journal of Managed Care and Specialty Pharmacy

American Drug Utilization Review Society (www.adurs.com)
A non-profit entity whose mission is to provide leadership forum for individuals active in drug utilization review (DUR) from the 50 state and District of Columbia Medicaid programs. The organization shares information, develops skills, and provides training to help members efficiently and effectively perform DUR duties.

- Hosts an annual meeting in February

American Medicaid Pharmacy Administrators Association
Helps to disseminate information about valid pharmacy issues and is affiliated with three regional associations: the Eastern Medicaid Pharmacy Administrators Association, the Western Medicaid Pharmacy Administrators Association, and the Southern Medicaid Pharmacy Administrators Association.

Center for Health Care Strategies (www.chcs.org)
A non-partisan organization that facilitates problem-solving exchanges and peer learning among a diverse range of health care stakeholders to improve access, integrate fragmented services, reduce avoidable expenditures, and link payment with quality.

- Offers webinars through the year

Center for Evidence-Based Policy (https://centerforevidencebasedpolicy.org/)
A center within Oregon Health & Science University that hosts collaboratives that address Medicaid policy challenges, including the Drug Effectiveness Review Project (DERP), Medicaid Evidence-Based Decisions (MED) Project, and the State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D).

Institute for Clinical and Economic Review (www.icer-review.org)
Independent, non-partisan research organization that objectively evaluates the clinical and economic value of prescription drugs and other health care innovations.

- Health technology assessments and evidence assessment meetings are public
Massachusetts Institute of Technology’s NEW Drug Development ParadIGmS Initiative Financing and Reimbursement of Curse in the US [MIT NEWDIGS FoCUS] Project (https://newdigs.mit.edu)
Multi-stakeholder collaboration to address the need for new, innovative financing and reimbursement models for durable/curative therapies that ensure patient access and sustainability.

Medicaid and CHIP Payment and Access Commission (www.macpac.gov)
A non-partisan legislative branch agency that provides policy and data analysis.

National Academy for State Health Policy (https://nashp.org)
Non-partisan forum of policymakers throughout state governments, learning, leading and implementing innovative solutions to health policy changes.
- Hosts an annual meeting in the summer and webinars throughout the year
- Maintains the Center for State Rx Drug Pricing, a clearinghouse of resources developed for states to address high drug prices

National Association of Medicaid Directors (www.medicaiddirectors.org)
An independent, bi-partisan, non-profit professional organization representing the leaders of state Medicaid agencies across the country. NAMD’s mission is to support Medicaid Directors in program administration, including an area of focus on prescription drugs.
- Hosts an annual meeting in the fall and webinars throughout the year
Appendix B.
Key Informants and Reviewers

Key Informants:

Center for Medicare and Medicaid Services, Disabled and Elderly Health Programs
- Michael Nardone, MPA, Director
- Alissa DeBoy, Deputy Director
- John Coster, PhD, RPh, Director, Division of Pharmacy
- Wendy Tuttle, Acting Deputy Director, Division of Pharmacy
- James Golden, PhD, Director, Division of Managed Care Plans

Arizona Health Care Cost Containment System
- Thomas Betlach, MPA, former Medicaid Director

Connecticut Department of Social Services
- Kate McEvoy, JD, Medicaid Director
- Robert Zavoski, MD, MPH, Medical Director
- Herman Kranc, RPh, Pharmacy Director

Massachusetts Medicaid
- Paul Jeffrey, PharmD, Pharmacy Director

Oklahoma Health Care Authority
- Nancy Nesser, JD, PharmD, Pharmacy Director

Texas Health and Human Services Commission, Pharmacy Vendor Drug Program
- Gina Muniz, CBCP, MCP, CTCM, Deputy Director of Pharmacy
- Priscilla Parrilla, Director of Pharmacy Operations

Department of Vermont Health Access
- Nancy Hogue, PharmD, Pharmacy Director
Reviewers:

Center for Medicare and Medicaid Services, Disabled and Elderly Health Programs, Division of Pharmacy
- CAPT Michael Forman, RPh, Acting Deputy Director

Health System Transformation
- Joshua Slen, MPA, President

National Academy for State Health Policy
- Jennifer Reck, MA, Project Director

National Association of Medicaid Directors
- Jack Rollins, MPH, Senior Policy Analyst