Key Coverage and Reimbursement Considerations for Specialty Drugs in an Evolving Medicaid Landscape

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This research paper identifies three key elements that state and federal lawmakers should consider when implementing new reimbursement methodologies for pharmacy-benefit covered drugs in Medicaid.

1. Current efforts to implement a new reimbursement benchmark and related dispensing fee rates are imperfect, because they do not appropriately account for specialty drugs
2. Stakeholders need to better understand the complexity of specialty drug distribution and related patient management requirements to ensure optimal health outcomes
3. The expanding enrollment in Medicaid, coupled with the increasing number of specialty drugs entering the market, lends more urgency to the task of ensuring specialty drugs are correctly reimbursed

Specialty drugs are highly complex pharmaceuticals that are increasingly used to treat chronic medical conditions. These unique pharmaceuticals are generally created from biologic materials rather than synthetic chemicals. The complexity, expense and time required to produce these medicines is vastly different than that of traditional pharmaceuticals, which can be manufactured in a matter of hours or days.

Among the more costly and complex specialty drugs are medicines derived from human blood plasma, a rich source of therapeutic proteins. Plasma–derived medicines are used to treat rare, chronic and life-threatening diseases—including hemophilia, immune deficiencies and alpha1-antitrypsin deficiency—for which there are few, if any, traditional treatments. Producing these medicines is lengthy and complex: their source material must be obtained from millions of qualified plasma donors; rigorously tested for pathogens; then fractionated and purified to extract and safeguard the therapeutic proteins for patient use. Plasma-derived therapies also require unique distribution channels, such as specialty pharmacies and customized patient services to ensure optimal health outcomes.

Specialty pharmacies are high-touch, full-service pharmacies that serve as a unique access channel for specialty drugs. Most payers, including state Medicaid programs, use specialty pharmacies to manage care for patients needing specialty drugs. For example, 38 percent of Medicaid managed care plans mandate that patients obtain hemophilia factor therapies from specialty pharmacies.[1]

New reimbursement benchmark and dispensing fees are imperfect

The increasing use of specialty drugs and biologics, such as plasma-derived medicines, is one of the factors driving state and federal governments to more closely examine how drugs are reimbursed within Medicaid. An emerging reimbursement metric is Actual

[1] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012

Acquisition Cost (AAC). This benchmark bases reimbursement on cost data collected directly from pharmacy invoices. Proponents of AAC claim that it is a more appropriate benchmark because it reflects the actual selling price of the product as compared to a list price benchmark. States are conducting surveys to gather data to inform the calculation of AAC. Although specialty pharmacies are included in the sample, the data is often excluded because it falls within the top decile, which is considered an outlier for AAC data collection purposes. In implementing AAC-based reimbursement, some stakeholders note that dispensing fees have historically been too low, and that higher drug reimbursement has been used to offset these deficits. However, most states implementing AAC do not differentiate between dispensing fees for specialty drugs and non-specialty drugs.

Specialty drug distribution and related patient management requirements are unique

As both federal and state governments reexamine how they pay for drugs dispensed through the pharmacy channel, policymakers should take into account that specialty drugs are different from traditional pharmaceuticals. The customized patient services and specialized handling these medicines require are key factors to consider in setting reimbursement levels. Adequate reimbursement is one of the ways to ensure that patients have access to needed medications.

Changing Medicaid landscape creates an urgent need to ensure specialty drugs are correctly reimbursed

With the passage of health reform in 2010,[2] state Medicaid programs are expected to enroll approximately 11 million new beneficiaries by 2022,[3] making the delivery of care and controlling costs even more challenging for states. Coupled with this changing Medicaid landscape is the increasing number of specialty drugs approved by the U.S. Food and Drug Administration in recent years, with more drugs in the pipeline. These factors create the need to ensure specialty drugs are correctly reimbursed using an appropriate reimbursement benchmark and adequate dispensing fee.

With a particular focus on plasma-derived medicines, this paper will explore:

- Unique characteristics of specialty drugs
- Services offered by specialty pharmacies to address the unique needs of patients
- Emerging reimbursement methodologies in the Medicaid program
- Factors for states to consider when pursuing new pharmacy reimbursement benchmarks

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[2] Patient Protection and Affordable Care Act, enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010, enacted on March 30, 2010, collectively known as the Affordable Care Act. Affordable Care Act of 2010, Pub. L. No. 111-148.

[3] Congressional Budget Office."Estimates for the Insurance Coverage Provisions of the Affordable Care Act Updated for the Recent Supreme Court Decision." July 2012.

Basics of Specialty Drugs

Specialty drugs are prescription medications that are used to treat complex, chronic medical conditions such as multiple sclerosis, hemophilia and rheumatoid arthritis. They require special manufacturing, handling, storage, administration, monitoring and other wrap-around services. These drugs are the result of continued advances in drug development and design, often making them more costly than traditional pharmaceuticals. As an increasing number of specialty drugs have been approved by the U.S. Food and Drug Administration (FDA) in recent years, it has become the fastest growing segment of drug-spend in the United States.

Top Traditional and Specialty Drug Therapeutic Categories by Commercial Plan Spend (2011 per Member Year)[5]

	Traditional	Specialty
Rank	Class	Class
1	Diabetes	Inflammatory Conditions
2	High Blood Cholesterol	Multiple Sclerosis
3	High Blood Pressure/Heart Disease	Cancer
4	Depression	HIV
5	Asthma	Growth Deficiency
6	Ulcer Disease	Anticoagulants
7	Attention Disorders	Hepatitis C
8	Infections	Transplant
9	Mental/Neurological Disorders	Respiratory Conditions
10	Pain	Pulmonary Hypertension

The chart above highlights the top traditional and specialty drug categories in 2011, as ranked by plan spend. Although not in the top ten specialty therapeutic categories, drugs for the treatment of bleeding and clotting disorders and immune deficiencies are generally considered as specialty, with approximately 80 percent of commercial plans classifying these therapies as specialty drugs.[6]

[5] The Express Scripts Research and New Solutions Lab. 2011 Drug Trend Report. April 2012.

[6] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012

Defining Specialty Drugs

Though many drugs are placed in the "specialty" drug category, there is no official definition of a specialty drug, leaving payers to develop their own criteria for the classification of these products. In 2011, payers cited route of administration, special storage and handling requirements, and cost as three common factors used to classify a specialty drug.[7] These characteristics and others make specialty products unique in the pharmaceutical and biologics marketplace.

Route of administration—The route of administration often plays a primary role in a drug's classification as a specialty product. Traditionally, infused and injectable therapies administered in a physician office or infusion clinic have comprised the majority of specialty drugs. However, many orals and self-administered injectable drugs are also now considered specialty.

These self-administered injectables sometimes require the use of a home nurse (for certain patients and disease states) and the proper training of patients to ensure appropriate administration and optimal therapeutic benefit. The use of home nurses and proper training of patients is of particular importance for those receiving routine administration of complex, plasma-derived products.

Special storage and handling requirements—The production of specialty drugs typically entails a lengthy and intricate manufacturing process. Many specialty drugs are comprised of biologic materials, needing special storage and handling requirements (e.g., refrigeration) to maintain the integrity of the product. For instance, variable temperatures may affect potency of plasma-derived products, and therefore decrease efficacy.

Cost—Another distinction between traditional and specialty drugs is the difference in drug spend. Due to the complexities in manufacturing, specialty drugs tend to cost more than traditional drugs. Payers often place specialty drugs on their formulary's designated specialty tiers, with the patient responsible for sharing a larger portion of the drug's cost.

Routine patient monitoring—Careful clinical monitoring and patient-specific dosing is necessary to ensure that patients effectively manage complex diseases with little or no adverse effects. This type of patient monitoring differs greatly from that of traditional, small molecule, non-biologic medications.

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[7] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012.

Therapeutic area—Specialty medications treat a variety of conditions, but most often treat complex acute or chronic medical conditions/illnesses, genetic disorders, and/or rare diseases.

Coverage and management—Specialty drugs have varying coverage structures within benefit plans and may be distributed through several channels, posing unique challenges for coverage and management of these products. Specialty drugs may be covered under either the pharmacy benefit or the medical benefit, and in some cases, under both. They may be distributed by retail pharmacies, specialty pharmacies, mail-order pharmacies, a physician's office, or a home health agency.[8]

Specialized or limited product distribution—Unlike traditional drug distribution channels, the complexity of specialty drug distribution, handling, and patient support leads many health plans to adopt a limited pharmacy network that may contain only one or a few specialty pharmacies.[9]

[8] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012.

[9] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012

Specialty Pharmacies

Specialty pharmacies offer services to address the diverse needs of patients taking specialty drugs—services that differ greatly from those offered by traditional retail community pharmacies and mail-order pharmacies. While specialty pharmacies focus on dispensing specialty products, any licensed pharmacy, such as retail, mail-order, or specialty, may dispense a specialty drug as long as the product is available through an authorized wholesaler. However, specialty pharmacies typically have more sophisticated infrastructure to handle the complexities of specialty drugs and patient management.

Specialty pharmacies serve and support health plans, manufacturers, providers, and patients in a variety of capacities. The table below provides an overview of the services typically offered by specialty pharmacies.

Description of Services Offered by Specialty Pharmacies	
Increase Utilization of Preferred Therapies	Supports plans' goal of increasing utilization of preferred drugs within specific specialty classes. Specialty pharmacies generally do this by calling providers to suggest preferred drugs and enforcing compliance to plan formulary and prior authorization criteria.
Patient Access	Increases patient access to specialty drugs through various delivery options, including designated specialty brick and mortar pharmacies, home or work delivery, or pick-up at a local pharmacy.
Access to Support Programs	Addresses cost sharing concerns by informing patients and providers of manufacturer-supported programs such as patient assistance programs, copayment assistance programs and reimbursement hotline services.
Product Integrity	Ensures product integrity in the supply chain and allows manufacturers to select the most appropriate specialty pharmacy partner(s) to inform manufacturing needs, data collection and clinical insight.
Medication Compliance and Health Education	Encourages medication compliance (including adherence and persistence) through patient care team support services. Provides education materials about diseases and helps train patients on new medication regimens.
Data Collection	Partners with manufacturers to collect claims data on patient utilization of product and relevant health status for use in value messaging to providers and payers regarding competitive advantage, such as adherence and health outcomes (e.g. reduced hospitalizations). Specialty pharmacies can also support manufacturer Risk Evaluation & Mitigation Strategies programs by collecting data for regulatory review.
Insurance Benefit Verification	Reviews patient's insurance to ensure coverage of products prescribed and coordinates with provider and plan to approve prior authorization requirements.
Case Coordination and Management	Creates a care team to support patients in complying with medication regimens correctly (including adherence and persistence), ensure refills are picked-up and utilized, reviews storage and handling requirements, and addresses side effects and complications from comorbid conditions, among other related issues to ensure optimal clinical health outcomes. Specialty pharmacies may review prescription claims history to identify opportunities for care intervention. For specialty pharmacies with brick and mortar stores, on-site staff provides training on administering specialty medications (e.g. injection training, starter kits, etc.).
Operational Efficiencies	Conducts claims processing, prior authorization reviews, and patient appeals.

Many specialty pharmacies design customized programs for patients with certain complex and debilitating diseases. Bleeding disorders and immune deficiencies are common areas of focus for specialty pharmacies.

Case Study: Custom Specialty Pharmacy Services for Hemophilia Patients

Treatment costs for a patient living with hemophilia can be as much as $1 million annually,[10] while the cost of medications can exceed $300,000 annually.[11] Specialty pharmacies offer customized services to manage care and treatment costs for this patient population.

Diplomat's Hemophilia Navigator™[12]	
Pharmaceutical Care Review	Pharmacists and nurses thoroughly review each patient's medical history, drug history, and laboratory values to verify that treatment ordered is appropriate.
Clinical Care Review	Clinical staff acts under the direction of the Hemophilia Treatment Center (HTC) to individualize care.
Educational Protocol	All educational guidelines are age specific and aligned to support and reinforce the teaching provided at the HTC.
Operational Overview	Each referral is assigned to a Patient Care Representative (PCR) that communicates reimbursement issues (including determining the lowest cost of care), educate on policies and procedures, and coordinates timely and proper delivery of products.
Navigator Patient Care System (eNAV™)	An electronic patient care system that features medication history tracking and related cost savings—patient care is customized instantly.
Delivery	All drugs shipped are packaged to protect the integrity of the drug. Shipments are monitored and tracked internally as well as through the shipping company's web site.
Inventory Management and Refills	Patient specific inventory is kept on-hand to ensure quick and prompt deliveries; an emergency supply procedure includes around the clock (24/7) delivery. In addition, an auto-refill program is set up for each patient which includes contacting the patient directly to verify that the refill is needed or if necessary.

Programs such as Diplomat's aim to: (1) reduce adverse events, (2) improve patient health outcomes, and (3) reduce health plan and patient costs. For example, CoramRx™ Specialty Pharmacy program targets patients with hemophilia and cites savings of $6,000 monthly per patient when they are enrolled in their case management program.[13]

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[10] "Insights 2012: Advancing the Science of Pharmacy Care". CVS Caremark. 2012.

[11] Gilbert, A., and Tonkovic, B. (2011). Case report of specialty pharmacy management of hemophilia. *Journal of Managed Care Pharmacy*, 17(2), 175-76. http://www.amcp.org/data/jmcp/175-176.pdf.

[12] Hemophilia Navigator Program. Diplomat Specialty Pharmacy. Available at: http://hemophilianavigator.com/about/hemophilia-navigator/ (accessed July 6, 2012).

[13] Gilbert, A., and Tonkovic, B. (2011). Case report of specialty pharmacy management of hemophilia. *Journal of Managed Care Pharmacy*, 17(2), 175-76. http://www.amcp.org/data/jmcp/175-176.pdf.

Custom Specialty Pharmacy Services for Hemophilia Patients

Patient: 21-year-old male with severe hemophilia A

Patient/Disease Complications	Current Treatment	Intervention	Disease Management Program	Results Three Months After Nurse Visit
• Multiple target joints (1.75 bleed/month) • Obese • Noncompliant with regimen • Lack of knowledge regarding disease and treatment • Social/environmental issues: » Unemployment » Sedentary lifestyle » Dual residencies	• Clotting factor as primary prophylaxis • Admitted to discontinuing primary prophylaxis use • Treated only severe bleeds with incorrectly high dosing attempting to expedite healing • Two months of clotting factor inventory (estimated value of $100,500)		• Initial phone assessment completed with a hemophilia specialist and patient completes a self-management questionnaire • Disease benchmarking period begins and home visit is warranted • Hemophilia nurse specialist provides education focused on disease severity, mechanism of joint destruction from bleeds, and consequences of treatment delays/no compliance • Overall treatment plan and patient agreed to continue enrollment in disease management program • Conducted monthly telephonic assessment calls to monitor bleeding episodes and other lifestyle indicators	• Patient demonstrated compliance to treatment plan • Bleeding into target joints reduced (1 bleed in three months) • Patient reported wearing medical alert identifier • Reduced average monthly drug costs by $6,490

Case Study: Custom Specialty Pharmacy Services for Patients Needing Immunoglobulin (IG) Therapy

IG products treat a variety of autoimmune diseases, infections and infection-related diseases, neuroimmunologic disorders, and primary and secondary immune deficiencies. Given the wide range of disease severity and patient characteristics of the IG treatment population, many specialty pharmacies offer customized services to manage care and treatment costs.

KabaFusion IVIG Services[14]	
Enrollment	Coordinators manage all insurance authorization, eligibility and coverage benefits. Proactively manage re-authorization to avoid any disruption in care.
Individualized Patient Care Plans	Pharmacists work closely with physicians and evaluate every patient's medical record to select appropriate medication. If not specified by a physician, therapy is individualized accounting for unique patient characteristics.
At Home Nurse	Registered nurses skilled in intravenous IG and home infusion accompany patient during the entire infusion and are dedicated to having continuity of care with the same nurse every time.
Total Care Management	Outcomes evaluation and tracking of all patients. Continuous case management of chronic patient by registered nurse and pharmacist during and between treatments
Patient Assistance	Intake team is dedicated to provide financial counseling as needed. All manufacturer and KabaFusion patient assistance plans are optimized.
Drug Information	KabaFusion is contracted with the University of Iowa Drug Information Service for real-time drug information for patients, physicians, and payers. On-line references are available 24/7.
Pharmacists and Nurses Available 24 Hours	Managed by registered pharmacists who specialize in home infusion therapy.

[14] KabaFusion. IVIG Services. Available at: http://www.kabafusion.com/Home%20Page/IVIG-Therapy-Provider.html (accessed July 17, 2012).

Changing Landscape for Medicaid Reimbursement

Access to affordable care coupled with rising costs were two leading drivers of the passage of the Affordable Care Act of 2010.[15] As a result of health care reform, state Medicaid programs are expected to enroll approximately 11 million new beneficiaries by 2022.[16] With these new covered lives, state Medicaid programs are seeking innovative ways to balance costs and patient access to medically valuable treatments.

Looking to save costs on prescribed drugs, many states are considering new reimbursement benchmarks for drugs covered under the Medicaid pharmacy benefit. When exploring and rolling out new payment mechanisms, policymakers will need to recognize that specialty drugs differ from traditional pharmaceuticals, not only in their makeup but also in the way they are administered. The legitimate costs of specialty medication administration must be considered in setting reimbursement benchmarks to help ensure that patients will have access to these therapies.

Reimbursement Benchmarks

State Medicaid agencies have historically used benchmarks such as Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC) to reimburse for drugs covered under the pharmacy benefit. Reimbursement based on a percentage of AWP (e.g., AWP -18%) is the most common of the pharmacy reimbursement methodologies, with 45 state Medicaid agencies using this methodology in the first quarter of 2011.[17]

AWP-based reimbursement has been subject to scrutiny because it is not viewed as being representative of the true market price for drugs, as AWP does not include any discounts or rebates offered by manufacturers. Payers are now seeking an alternative to AWP-based reimbursement that more accurately captures a pharmacy's drug acquisition costs.

One emerging reimbursement metric is Actual Acquisition Cost (AAC). This benchmark bases reimbursement on data collected directly from pharmacy invoices. Proponents of AAC claim that it is a more appropriate benchmark because it reflects the actual selling price of the product as compared to a list price benchmark such as AWP. Opponents believe that it is not practical to find a true median or mean of pharmacy acquisition costs without significantly underpaying some smaller pharmacies that do not have access to

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[15] Patient Protection and Affordable Care Act, enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010, enacted on March 30, 2010, collectively known as the Affordable Care Act. Affordable Care Act of 2010, Pub. L. No. 111-148.

[16] Congressional Budget Office."Estimates for the Insurance Coverage Provisions of the Affordable Care Act Updated for the Recent Supreme Court Decision." July 2012.

[17] Office of the Inspector General. "Replacing Average Wholesale Price: Medicaid Drug Payment Policy." July 2011.

the sizeable discounts secured by large retail pharmacy chains. Despite these concerns, payers are now looking at AAC-based reimbursement as a viable benchmark for Medicaid covered prescription drugs.

State Medicaid agencies are the first payers to conduct surveys in order to implement the AAC-based reimbursement methodology. Alabama[18] began AAC-based pharmacy reimbursement in late 2010; Oregon[19] and Idaho[20] followed suit in 2011. Louisiana's AAC benchmark more recently took effect in September 2012.[21] Additionally, California[22] and New York[23] have passed legislation to establish AAC-based reimbursement, likely in 2013.

Although many state AAC surveys have included specialty pharmacies in their sample, the methodology developed often results in the exclusion of these data points as they are considered "outliers."[24] The low volume of claims for specialty drugs, as compared with traditional drugs, leads to concerns about the validity of the survey sample. When specialty pharmacies are included in surveys, their data is often excluded because it falls within the top decile, which is considered an outlier for AAC data collection purposes. When implemented, AAC-based reimbursement is utilized across all pharmacies, even though the actual costs of specialty pharmacies are not included in the reimbursement metrics.

In addition to these state-based AAC surveys, the Centers for Medicare & Medicaid Services (CMS), is encouraging remaining states to consider an AAC-based reimbursement benchmark based on an ongoing national (rather than state-based) survey of pharmacy acquisition cost data. This survey, known as the National Average Drug Acquisition Cost (NADAC) survey, offers states an alternative to conducting their own survey while still implementing an acquisition cost-based pharmacy reimbursement benchmark for brand and generic drugs. The availability of this data source may accelerate the transition from AWP to AAC –based reimbursement for pharmacy benefit products in Medicaid. However, the NADAC does not currently include the surveying of specialty pharmacies. States must amend their plans or pass legislation to change their reimbursement methodology. Therefore, a migration to AAC-based reimbursement, especially for specialty pharmacy, may take time.

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[18] Alabama Medicaid Agency. "CMS approves AAC drug pricing method, dispensing fee increase." September 17, 2010.

[19] Office of the Inspector General. "Replacing Average Wholesale Price: Medicaid Drug Payment Policy." July 2011.

[20] H.B. 221 was introduced by The Healthcare and Welfare Committee. H.B. 260 was introduced by The Ways and Means Committee.

[21] Louisiana Medicaid Department. LA Medicaid Pharmacy Reimbursement Notice to Providers. http://www.lamedicaid.com/provweb1/recent_policy/Pharmacy%20Reimbursement%20Notice.pdf.

[22] California AB 97. SEC. 97.5. Section 14105.451.

[23] New York State Department of Health. "Authority to Collect Pharmacy Acquisition Costs."

[24] The Alabama Medicaid Agency. "Cost of Dispensing Prescription Drugs in Alabama: Final Report." January 6, 2010.

Dispensing Fees

Dispensing fees serve a crucial role, as they cover the cost of business for the pharmacy, including: staffing, operations and overhead, preparing and dispensing medications, and assuring appropriate use of medication. The following table offers more details for each of the elements that are considered in calculating the dispensing fee.

Elements of Pharmacy Service Costs[25]	
Staffing	• Salaries (pharmacists, technicians, managers, cashiers, etc.) • Licensure and/or continuing education for pharmacists, technicians
Operations and Overhead	• Rent or mortgage • Cleaning, repairs and security • Utilities (heat, light, telephones) • Computer systems, software, and maintenance • Marketing and advertising • Accounting, legal, and professional fees • Insurance, taxes, and licenses • Interest paid on pharmacy-related debt • Depreciation • Complying with federal and state regulations (e.g., HIPAA) • Corporate overhead (central management, etc.)
Preparing and Dispensing Prescriptions	• Prescription dispensing materials (packages, labels, pill counters, etc.) • Compounding • Special packaging (unit dose, blister packs) • Special supplies (syringes, inhalers)
Assuring Appropriate Use of Medication	• Drug use review • Consumer/patient counseling • Consulting with prescribers • Disease management • Education and training

In discussion surrounding the implementation of AAC-based reimbursement, some stakeholders point out that dispensing fees have historically been too low, and that higher drug reimbursement has been used to offset these deficits.[26] Some states have recognized the inadequacy of maintaining existing dispensing fees when paired with the implementation of AAC-based reimbursement. In Alabama, the dispensing fee for all pharmacies increased from $5.40 to $10.64 following the implementation of acquisition cost-based reimbursement.

[25] National Association of Chain Drug Stores, Issue Brief, "Elements of a Pharmacy Dispensing Fee." October 2004. Accessed October 2, 2012 http://ovha.vermont.gov/budget-legislative/appendix3b.pdf.

[26] Fein, Adam J. Pembroke Consulting. 2011–12 Economic Report on Retail and Specialty Pharmacies. January 2012.

Many critics argue that the higher dispensing fees do not always adequately cover the associated costs specialty pharmacies incur for the added services they provide when dispensing specialty drugs.[27] As discussed, dispensing costs for specialty pharmacies are typically higher than traditional pharmacies due to the operations and infrastructure needed to execute these high-touch services—case management, product handling, medication compliance, etc. Survey data from other states shows that specialty pharmacy dispensing fees average $59.18,[28] and that shipping costs alone for these drugs exceed $12 on average.[29]

Historically, states have not differentiated dispensing fees for specialty drugs. As the following table depicts, even states that have implemented an AAC-based reimbursement methodology have not differentiated dispensing fees for specialty/non-specialty drugs or for retail pharmacy/specialty pharmacy. Iowa appears to be the only state considering a separate dispensing fee for specialty drugs in their move to AAC. The state's policymakers are still reviewing data and based on survey results, Iowa's Medicaid program may consider the additional costs to dispense specialty drugs in the development of a dispensing fee.

[27] Specialty Pharmacy News. "Proposed Methodology Ignores Specialty Pharmacies, May Have Unintended Effects." September 2010.

[28] Myers and Stauffer, LLC. "Survey of the Average Cost of Filling a Medicaid Prescription in the State of Minnesota." December 2006.

[29] Specialty Pharmacy News. "Proposed Methodology Ignores Specialty Pharmacies, May Have Unintended Effects." September 2010.

Dispensing Fees in States with AAC-Based Medicaid Pharmacy Reimbursement			
State	**Dispensing Fee (Pre-AAC implementation)**	**Dispensing Fee (Post-AAC implementation)**	**Differentiation for Specialty Pharmacy**
Alabama	$5.40[30]	$10.64[31]	No[32], but the fee is reviewed periodically for reasonableness and, when deemed appropriate by Medicaid, may be adjusted.[33]
Oregon	$3.50 (retail pharmacies) or $3.91 (institutional pharmacies)[34]	Tiered fee structure based on a pharmacy's total annual claims volume: • >30,000 claims a year = $14.01 • 30,000-49,999 claims per year = $10.14 • 50,000+ claims per year = $9.68 • Pharmacies that fail to respond to the annual survey will default to the $9.68 dispensing fee.[35]	No[36]
Idaho	$4.94[37]	Tiered fee structure based on a pharmacy's total annual claims volume: • >39,999 claims a year = $15.11 • 40,000-69,999 claims a year = $12.35 • ≤70,000 claims a year = $11.51[38]	No[39]
Iowa	$6.20[40]	Cost of dispensing surveys completed in August 2012.[41] The Department expects the initial dispensing fee to be within the range of $10.00 to $11.10.[42]	Based on the survey results, the agency will consider any additional costs to dispense specialty drugs.[43]
Louisiana	$5.77[44]	$10.13[45]	No[46]
California	$7.25 ($8 for skilled nursing facilities)[47]	Not yet established	Not yet determined
New York	$3.50[48]	Not yet determined; cost of dispensing survey ongoing.[49]	The agency will minimize any adverse impact on small businesses, and work with small businesses to develop an appropriate dispensing fee that accurately reflects the costs associated with this amendment.[50]

[30] The Alabama Medicaid Agency. "CMS approves AAC drug pricing method, dispensing fee increase." September 17, 2010. http://medicaid.alabama.gov/news_detail.aspx?ID=3898.

[31] The Alabama Medicaid Agency. "CMS approves AAC drug pricing method, dispensing fee increase." September 17, 2010. http://medicaid.alabama.gov/news_detail.aspx?ID=3898.

[32] Alabama State Plan Amendment AL-10-008. http://www.medicaid.state.al.us/documents/program-RX/AAC/Approved_State_Plan_Amend_9-16-10.pdf.

[33] Alabama State Plan Amendment AL-10-008. http://www.medicaid.state.al.us/documents/program-RX/AAC/Approved_State_Plan_Amend_9-16-10.pdf.

[34] Kaiser Family Foundation. Managing Medicaid Pharmacy Reimbursement: Current Issues and Options. September 2011. http://www.kff.org/medicaid/upload/8234.pdf.

[35] Oregon Health Authority. Pharmacy Reimbursement Questions and Answers. http://www.oregon.gov/oha/pharmacy/reimburse-method/docs/aaac-qa.pdf.

[36] Oregon State Plan Amendment Transmittal #10-13. http://www.oregon.gov/oha/pharmacy/reimburse-method/docs/spa2010-13.pdf

[37] Centers for Medicare and Medicaid Services. Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2011. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/4QStatePrescriptionDrugRes.pdf.

[38] Idaho Department of Health and Welfare. Pharmacy Reimbursement Changes Effective September 28, 2001 Frequently Asked Questions. http://www.healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/PharmacyReimbChangesFAQs.pdf.

[39] Idaho H.B. 260. [40] Iowa Department of Human Services. Informational Letter No.1163. August 20, 2012. http://www.ime.state.ia.us/docs/1163_PharmacyDispensingFeeIncrease.pdf.

[41] Iowa Department of Human Services. Pharmacy Cost of Dispensing Survey. http://www.mslciowa.com/CostofDispensingSurvey.htm.

[42] Iowa Department of Human Services. Notice of Intended Action ARC 0259C. http://www.dhs.state.ia.us/policyanalysis/rulespages/RuleDocuments/RulesInProcess/0259C.pdf.

[43] Iowa Department of Human Services. Notice of Intended Action ARC 0259C. http://www.dhs.state.ia.us/policyanalysis/rulespages/RuleDocuments/RulesInProcess/0259C.pdf.

[44] State of Louisiana Department of Health and Hospitals. Revised Louisiana Maximum Allowable Cost (LMAC) Methodology. January 25, 2010. http://www.lamedicaid.com/provweb1/Recent_policy/Pharm_Letter.pdf.

[45] Louisiana Medicaid. LA Medicaid Pharmacy Reimbursement Notice to Providers. http://www.lamedicaid.com/provweb1/recent_policy/Pharmacy%20Reimbursement%20Notice.pdf.

[46] Louisiana Medicaid. LA Medicaid Pharmacy Reimbursement Notice to Providers. http://www.lamedicaid.com/provweb1/recent_policy/Pharmacy%20Reimbursement%20Notice.pdf.

[47] Centers for Medicare and Medicaid Services. Medicaid Prescription Reimbursement Information by State – Quarter Ending June 2012. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/ReimbursementChart3Q2012.pdf.

[48] Centers for Medicare and Medicaid Services. Medicaid Prescription Reimbursement Information by State – Quarter Ending June 2012. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/ReimbursementChart3Q2012.pdf.

[49] New York State Department of Health. NYS Medicaid Average Actual Acquisition Cost and Cost of Dispensing Project - Frequently asked Questions. http://www.health.ny.gov/health_care/medicaid/program/aac_cod/index.htm.

[50] New York State Department of Health. Authority to Collect Pharmacy Acquisition Costs. January 25, 2012.

Overall, dispensing fees have risen as states recognize that as AAC-based reimbursement more accurately reflects the actual ingredient cost. It is equally important that dispensing fees more accurately reflect the actual cost to dispense. However, the lack of consideration for specialty pharmacy dispensing cost differences appears to be an unintended consequence as states implement an acquisition cost-based reimbursement. If drug reimbursement is reduced to more closely approximate actual drug acquisition, the dispensing fee may need to be adjusted to reflect the true costs of specialty pharmacy services.

Medicaid Reimbursement Benchmarks—Implications and Considerations for Specialty Drugs

The use of specialty pharmacies in Medicaid to dispense and administer specialty drugs is widespread. Data indicates that over half (58%) of all Medicaid specialty drug claims are processed through a specialty pharmacy. States are also increasingly using specialty pharmacies as the sole dispensers for some therapies, with nearly two-thirds of all Medicaid programs mandating the use of specialty pharmacies to obtain products in at least one therapeutic category.[51] Hemophilia factor therapies serve as an example of such a mandate, with over one-third (38%) of Medicaid programs mandating the use of specialty pharmacies to obtain products in this therapeutic area.[12,53]

With specialty pharmacies serving as a major access channel for specialty drugs, it is important that state Medicaid programs evaluate how best to account for the unique costs associated with dispensing specialty drugs when developing new reimbursement methodologies and dispensing fee rates.

Considerations for Setting an Appropriate Pharmacy Reimbursement Benchmark

Whether states maintain their existing benchmark, transition to an acquisition cost-based benchmark or another methodology for Medicaid drug reimbursement, it is critical that policymakers ensure that the selected benchmark is appropriate for all classes of drugs.

State Medicaid programs may consider including specialty pharmacies in AAC or drug cost-related surveys in order to identify the true cost to dispense specialty drugs. As is highlighted in the following table, criteria for establishing an appropriate pharmacy reimbursement benchmark includes: availability, comprehensiveness, stability, timeliness, understanding, transparency, validity, and standardization.

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[51] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012.

[52] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012.

[53] EMD Serono. EMD Serono Specialty Digest™, 8th edition. 2012.

Criteria for an Appropriate Pricing/Reimbursement Benchmark Focuses on Accuracy, Availability and Timeliness

Criteria	Description
Available	The benchmark is publicly available for brand drugs
Comprehensive	The benchmark exists for both medical and pharmacy benefit products, as well as multiple acquisition channels (i.e., retail, mail order, and specialty pharmacy)
Stable	The benchmark is consistent over time (many years of data are available to assess stability and stability has been demonstrated)
Timely	The benchmark is updated in a timely manner (timely defined as updated at least monthly with data lag less than one quarter)
Understandable	The benchmark is explainable and understood by purchasers and payers
Transparent	The methodology for calculation and reporting are well known and sourceable
Valid	The benchmark bears an accurate relationship to product acquisition costs (high or medium scores receive a check mark)
Standardized	Reporting methodology and practices are consistent across manufacturers or providers (there is limited room for interpretation

Establish an Appropriate Dispensing Fee

The services, distribution channels, and costs associated with dispensing specialty drugs for patients with complex, chronic medical conditions are often significantly more than those for other disease states. State Medicaid programs may also consider establishing a separate dispensing fee that appropriately accounts for the services associated with the delivery of specialty drugs.

Ensuring Medicaid Beneficiary Access to Specialty Drugs

Despite signs of an economic recovery, cost pressures and cost containment remain a strong focus for state Medicaid programs. State Medicaid officials routinely cite limits on provider payments, benefits and strategies to control prescription drug spending as the most utilized cost savings strategies.[54] As federal and state policymakers develop these cost savings strategies, it is important that the distinction among pharmacy providers is recognized and appropriately considered in the implementation of any drug reimbursement benchmark.

This is especially important for specialty pharmacies, whose services differ greatly from those offered by traditional retail pharmacies. Specialty pharmacies manage costs and help ensure improved health outcomes for patients with complex, chronic conditions through patient medication compliance, proper delivery of drugs, and numerous other patient support services. These high-touch, full-service pharmacies serve a distinct role focused on patient-centered care. In conclusion, specialty pharmacies should be considered in the development of reimbursement benchmarks and dispensing fees to help ensure patient access to a full range of therapies and optimal health outcomes.

[54] http://www.kff.org/medicaid/upload/8380_ES.pdf.

Notes

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