

March 31, 2016

The Honorable Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-2345-FC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicaid Program; Covered Outpatient Drugs, CMS-2345-FC

Dear Mr. Slavitt:

Thank you for your ongoing efforts to improve the healthcare and services provided to Medicare and Medicaid beneficiaries. Innovatix is one of the nation's largest non-acute care group purchasing organizations, with a national membership of over 30,000 non-acute care providers, including approximately 650 long-term care pharmacies and 2,950 infusion providers. Based on insight from our provider members, Innovatix offers comments on the final rule affecting covered outpatient drugs entitled, "Medicaid Program; Covered Outpatient Drugs; Final Rule (CMS-2345-FC)" in the following areas: reimbursement and payment to pharmacies; differential methodology based on pharmacy type; Medicaid managed care organizations; and inhalation, infusion, instilled, implanted, and injectable drugs (known as "5i drugs").

Reimbursement and Payment to Pharmacies

In the rule, the Centers for Medicare & Medicaid Services (CMS) requires states to consider both the ingredient cost reimbursement and the professional dispensing fee when proposing changes for the reimbursement of Medicaid covered drugs. Under the new requirements, states must provide adequate data, such as a state or national survey of retail pharmacy providers or other reliable information, to support any proposed changes to the professional dispensing fee through the State Plan Amendment formal review process. The professional dispensing fee appropriately pays the pharmacy for the valuable services associated with dispensing, such as order receipt and processing, a pharmacist-conducted clinical review, assembling and filling the prescription, pharmacist consultant services, specialized packaging, delivery of the medication, and other related services. Therefore, Innovatix strongly supports the CMS's recognition in the rule that pharmacies must receive adequate revenue for *both* components: reimbursement for the ingredient cost and payment for the professional dispensing fee.

Recommendation: The CMS should closely monitor states, validate their methodologies, and take action to ensure compliance with the rule's requirement that states consider both the ingredient cost reimbursement and the professional dispensing fee when determining payment to pharmacies.

Differential Methodology Based on Pharmacy Type

In the rule, states have the option to adjust the reimbursement for provider type or services rendered. Innovatix applauds the CMS for requiring that a professional dispensing fee must reflect cost components related to both professional services and drug dispensing; however, the rule gives states

flexibility on how to set their professional dispensing fee, which raises concerns about how the rule will be implemented. Innovatix believes the CMS must ensure that states differentiate between long-term care (LTC) and retail community pharmacies (RCPs) when developing their methodologies for professional dispensing fees and reimbursement for ingredient costs. The CMS recognized many of these differences when it created minimum performance and service criteria under Medicare Part D for pharmacies providing services to beneficiaries residing in LTC settings.ⁱ In Medicare Part D, these LTC pharmacy requirements and service criteria include: comprehensive inventory and inventory capacity, pharmacy operations and prescription orders, special packaging, IV medications, custom compounding, pharmacist on-call service (24/7), delivery service (24/7), emergency medications (24/7), emergency log books, and miscellaneous reports, forms, and prescription ordering supplies.ⁱⁱ Additionally, LTC pharmacies are responsible for assisting facilities in complying with the CMS regulatory requirements for pharmacy services.ⁱⁱⁱ Providing these services are costly, as a recent analysis demonstrated that the median cost for an LTC pharmacy to dispense one prescription is \$13.54, which is reflective of additional services that are not part of a retail pharmacy transaction.^{iv} Innovatix believes the professional services performed by LTC pharmacies must be accounted for in the calculation of a professional dispensing fee.

Recommendation: The CMS should ensure states pay professional dispensing fees that appropriately account for the differential services performed by LTC pharmacies.

Medicaid Managed Care Organizations

In the rule, Medicaid Managed Care Organizations (MCOs) are permitted the flexibility to reimburse pharmacies for ingredients costs and establish payment for professional dispensing fees. As states increasingly rely on MCOs, the CMS should require MCOs to adhere to the same Medicaid fee-for-service requirements in this rule. Innovatix has long advocated that LTC beneficiaries need access to proper services to ensure optimal health outcomes and submitted similar comments to the CMS regarding the Medicaid and CHIP Managed Care Proposed Rule CMS-2390-P. In our comments, we recommended that the CMS adopt the Medicare Part D Long-Term Care (LTC) Pharmacy Performance and Service Criteria^v (described in the section above) for MCOs, which would establish the minimum requirements to become a network LTC pharmacy. We again call upon the CMS to adopt this policy for MCOs so that beneficiaries who require LTC pharmacy services receive quality services.

Recommendation: The CMS should require states to ensure that their MCOs provide pharmacies with reimbursement for ingredient costs and payment for professional dispensing fees at levels that are consistent with the rule's requirements for Medicaid. Further, the CMS should adopt the Medicare Part D LTC Pharmacy Performance and Service Criteria for MCOs.

5i Drugs

In the rule, the CMS establishes a definition of Average Manufacturer Price (AMP) for inhalation, infusion, instilled, implanted, and injectable drugs (5i drugs). Because these drugs are not generally dispensed through RCPs, many factors may impact the calculation of valid, stable AMPs for 5i drugs. In the rule, 5i drugs with 70% or more sales (based on NDC-9 units) to entities other than RCPs or wholesalers for drugs distributed to RCPs, qualify for the 5i AMP calculation. The CMS requires manufacturers to perform the 70% evaluation for 5i drugs on a monthly basis. While the CMS is clear about the application of the 70% threshold, the CMS does not address the implications for 5i drugs that

could switch between the 5i AMP and the standard AMP calculation from month-to-month. The shift between the 5i AMP and the standard AMP calculation could potentially result in abrupt and significant shifts in reimbursement and cause access issues for patients.

Recommendation: The CMS must closely monitor the new AMP policy for 5i drugs and take steps to ensure stability in the market. This should include ongoing analysis to detect wide variations that may occur when manufacturer reporting switches between the 5i AMP and the standard AMP calculation.

In conclusion, Innovatix broadly supports the meaningful reforms included in this proposed rule but urges clarification on the above concerns. Thank you for considering these important issues and please contact Shara Siegel, Director of Government Affairs at ssiegel@innovatix.com or (212) 901-1264 with any questions. Innovatix looks forward to working with the CMS and other stakeholders as the policies contained in the final rule are implemented.

Sincerely,



John P. Sganga, FACHE
Executive Vice President, GNYHA Ventures
President & CEO, Innovatix
President & CEO, Essensa

ⁱ Long Term Care Guidance. (Centers for Medicare & Medicaid Services, 2005). <<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/LTCGuidance.pdf>>

ⁱⁱ Ibid

ⁱⁱⁱ Title 42: Public Health. PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES. Subpart B—Requirements for Long Term Care Facilities. §483.60 Pharmacy services. <http://www.ecfr.gov/cgi-bin/text-idx?SID=2eba3a0a15212180f771ef34f7f3813e&mc=true&node=se42.5.483_160&rgn=div8>

^{iv} Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of Costs to Dispense Prescriptions in Independently Owned, Closed-door Long-term Care Pharmacies. J Manag Care Spec Pharm 20: 291-320, (2014).

^v Long Term Care Guidance. (Centers for Medicare & Medicaid Services, 2005).

<<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/LTCGuidance.pdf>>