THORN RUN PARTNERS
GOVERNMENT RELATIONS

Background Brief

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SUBJECT: Drug Pricing Levers: Least Costly Alternative, Inherent Reasonableness

I. EXECUTIVE SUMMARY

With the increased politicization of drug pricing, the Administration is reportedly contemplating regulatory changes it might undertake to address the issue, such as deploying least costly alternative (LCA) or inherent reasonableness authority.[1] However, both of these paths face considerable legal and political obstacles, and LCA policies likely would require legislation restoring HHS authority prior to implementation.

II. INHERENT REASONABLENESS

In 2005, CMS finalized an inherent reasonableness rule[2] that allowed – but, at the time, reserved – the application of the policy to Medicare Part B drugs. The policy can provide a recourse to CMS and contractors when existing payment methodologies yield reimbursements that are considered "grossly excessive or grossly deficient" and not reflective of factors such as "changing technology, increased facility with that technology, or changes in acquisition or production costs." An additional consideration is whether "payment amounts are grossly higher or lower than payment amounts made by other purchasers in comparable localities."[3]

The agency's 2005 rule cited the Medicare Modernization Act's average sales price (ASP) plus six percent policy as generally obviating the need to invoke its inherent reasonableness authority for modifying Part B drug reimbursement.[4] However, the agency said that "we are retaining our authority to apply inherent reasonableness to [Part B] drugs if the need arises."[5] The current Medicare Claims Processing Manual[6] for Medicare Administrative Contractors (MACs) and Fiscal Intermediaries (FIs) discusses contractor-led application of the policy to drugs and biologics, such as excluding more expensive drugs that contain preservatives from an AWP calculation for drugs in the same HCPCS group if the preservatives have "no effect on the quality of the drug."[7] CMS stipulates that carrier and FI adjustments based on inherent reasonableness may not be greater than 15 percent in a given year but can be subject to a multi-year phase-in and necessitate CMS notification.

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[1] Wilkerson, *Inside Health Policy*, Sept. 24, 2015, available here.
[2] 70 Federal Register No. 238, p. 73623, available here.
[3] CMS, Innovators' Guide to Navigating Medicare, 2010, available here.
[4] *Ibid.*
[5] *Ibid.*
[6] Chapters 17 and 23, available here and here.
[7] *Ibid.*

In 2012, CMS took steps in the durable medical equipment sector that reinforce its awareness of inherent reasonableness authority as an administrative lever at its disposal. The agency convened a meeting on the process' potential applicability to non-mail order diabetic testing supplies.[8] A 2012 Kaiser Family Foundation (KFF) deficit reduction compendium notes that "[a]lthough the American Taxpayer Relief Act of 2012 recently mandated equal payment for mail order and non-mail order diabetic testing supplies upon implementation of the national mail order competitive bidding program, CMS could apply the inherent reasonableness process to other items and services on an annual or other periodic basis."[9]

However, KFF also said that "identifying valid and reliable data justifying a payment reduction (or a payment increase in the case of 'grossly deficient' Medicare payments) may be a limiting factor in applying this authority." A 1996 HHS Office of the Inspector General (OIG) report also cited the resource intensive nature of applying inherent reasonableness authority, noting that with inherent reasonableness "often taking two to four years to implement, Medicare faces substantial losses in potential savings – certainly in the millions of dollars – if reduced drug prices cannot be placed into effect quickly." [10]

III. LEAST COSTLY ALTERNATIVE; ADDITIONAL POLICIES

The application of LCA policies to Medicare Part B drugs and biologics has attracted some renewed attention. Medicare used LCA policies from 1995-2010 for certain prostate cancer drugs but discontinued them in April 2010 after a 2009 court ruling against the agency's statutory authority to apply the policies to an inhalation drug.[11] This followed a period when the Congressional Budget Office included an expansion of LCA policies – to include viscosupplements for osteoarthritis – as a $490 million saver within its 2008 options for reducing the federal deficit.[12]

In 2012, the HHS OIG issued a congressionally requested report finding that, had the LCA policy not been rescinded, CMS would have saved $33.3 million in one year on clinically comparable luteinizing hormone-releasing hormone (LHRH) agonists for prostate cancer.[13] The report said that the lapse in LCA policies for these therapies changed utilization patterns toward more costly products and that "LCA policies may be a useful tool for conserving taxpayer funds, provided that patients retain access to appropriate care, but are not likely to be restored without legislative action." It recommended that CMS seek legislative authority to implement LCA policies for Part B drugs in "appropriate circumstances," with CMS partially concurring. Specifically, CMS said it reviewed its current authority and agreed that congressional authorization would be needed. CMS added that any

[8] 77 *Federal Register* No. 123, p. 38067, available here.
[9] Kaiser Family Foundation, Policy Options to Sustain Medicare for the Future, Jan. 29, 2013, available here.
[10] HHS OIG, "Appropriateness of Medicare Prescription Drug Allowances, May 1996, available here.
[11] Wilkerson, *Inside Health Policy*, Sept. 17, 2014, available here.
[12] CBO, Budget Options, Volume I: Health Care, December 2008, available here.
[13] HHS OIG, "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered under Medicare Part B," November 2012, available here.

such request would be included in the President's Budget request, without committing to doing so. The agency has not since proposed such a legislative change.

In the Medicare Payment Advisory Commission's (MedPAC) June 2015 Report to Congress[14], the Commission addresses the potential to resurrect LCA policies, among other options, but does not yet make a formal recommendation. Policy options include:

1) **LCA and functional equivalence policies** that would set Part B payment at the level of the least costly product within a product "group;"
2) **Consolidated payment codes** – used in Medicare from 2007-2008 – that establish payment based on volume-weighted ASP for a group of "similar" drugs; and
3) **Bundling drug costs** with administration and related inpatient or emergency services, possibly for oncology, under the Center for Medicare and Medicaid Innovation's (CMMI) demonstration authority or a legislative change.

The Commission expects that the first two approaches would necessitate legislation to "restore the Secretary's authority to establish the LCA or consolidated payment code policies." However, the agency may pursue bundling drug costs under its wide-ranging CMMI demonstration authority, which allows for expansion if proven successful.

MedPAC notes that such policies are resurfacing because the Commission perceives an opportunity to improve value by tying payment to clinical effectiveness and by explicitly considering therapeutic alternatives.[15] The policies' impact on drug prices hinges largely on their ultimate design. They are likely to be crafted with the goal of reducing overall drug expenditures and, depending on how products are grouped into treatment classes and assessed for "functional equivalence," may not be adequately nuanced to differentially reimburse treatments that bring added value. Additionally, LCA policies assume that treatments have comparators, which may not be applicable to highly innovative drugs most likely to be priced at a premium.[16]

IV. CONCLUSION

We hope this is a helpful update on possible regulatory avenues the Administration may consider if it were to proceed with a drug pricing plan. We would be happy to discuss further at your convenience.

[14] MedPAC, Report to Congress, June 15, 2015.
[15] *Ibid*.
[16] *Inside Health Policy*, Sept. 23, 2015.