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Client Alert

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CMS Medicaid Rule Greatly Restricts 2014 Mandatory Prescription Drug Coverage for "Expansion Population"

May Also Impact Calculation of Medicaid Rebates and Best Price

On July 15, 2013, CMS issued its Final Rule addressing prescription drug coverage for the Medicaid expansion population.[1] Among other things, the Final Rule defines the scope of the ten applicable "essential health benefits" required by the Patient Protection and Affordable Care Act (PPACA) to be provided to all new Medicaid beneficiaries, including the minimum requirements for the provision of prescription drugs to these beneficiaries. The Final Rule, however, dramatically restricts mandatory coverage of prescription drugs for the expansion Medicaid enrollees by essentially eliminating today's Medicaid requirement that states must cover each "covered outpatient drug" subject to a national rebate agreement. Although drugs provided to the new Medicaid expansion population will still be subject to manufacturer rebates, state Medicaid programs will not be required to cover all drugs subject to the national rebate agreement. Instead, states will only be required to cover a minimum of drugs consistent with the applicable "benchmark" plan in the state.

Background

A major innovation of PPACA was the significant expansion of Medicaid coverage across the country to all citizens with incomes at or below 138% of the federal poverty level. PPACA § 2001(a) is estimated to expand Medicaid to over 15 million Americans.[2] Importantly for the states implementing Medicaid expansion, PPACA commits the federal government to paying 100% of the cost of these newly enrolled beneficiaries for the next two years, slowly reducing the federal commitment to 90% in 2022 and thereafter.

One provision of the expansion that has not received much attention, however, is the requirement that states are only required to provide coverage to the expansion population equal to "Benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2)." Id. Section 1937 plans, also known as alternative benefits plans or "ABP" plans, have been a Medicaid option for eight years, but have not been widely used. There are estimated to be 28 states that either have already agreed to expand coverage, or are leaning toward doing so.[3] Each

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of those states will have to create one or more ABPs to provide coverage to those new beneficiaries.

The Medicaid ABP provision was introduced into the Medicaid statute (at §1937) through the Deficit Reduction Act of 2005 as a way to afford states with greater flexibility in their benefit design. Provided that states met designated benchmark or "benchmark-equivalent" coverage requirements (not addressed in detail here), the states were allowed to design new coverage, programs without regard to the "amount, duration and scope" or other uniformity requirements otherwise applicable to the Medicaid fee-for-service program. The benchmark plans from which the state may choose are:

- the standard Blue Cross Preferred Provider option offered through the Federal Health Benefits program;
- the state employee coverage generally provided to all state employees;
- commercial HMO coverage provided through the largest commercial plan in the state; or
- other coverage approved by the Secretary of HHS.[4]

These benchmark standards are coverage minimums, and states were allowed to provide broader coverage as they saw fit. Coverage for certain patient groups, such as the aged, blind and disabled populations, were exempted from the 1937 flexibility authority.

Because ABP plans were permitted to provide less coverage than standard fee-for-service Medicaid, however, patient advocates and beneficiary groups exerted pressure on the states not to reduce benefit levels. As a result, in the ensuing eight years fewer than a dozen such plans were proposed and implemented by the states.[5] The ABP plans, however, are anticipated to greatly expand in 2014 as Medicaid expansion begins.

Although Section 1937 contained several benchmark options which provided minimum benefit levels, minimum levels of prescription drug coverage were effectively undefined in Section 1937 (other by reference to the benchmark plans, many of which did not cover drugs at all). To clarify the scope of the ABP coverage, Congress through PPACA added ten additional coverage requirements, known as "Essential Health Benefits," or EHBs, one of which was "prescription drugs." 42 C.F.R. 440.437.[6] Congress, however, did not define the scope of drug coverage required, instead leaving it to CMS to further clarify how many drugs would have to be covered and under what conditions. CMS addressed this issue in the July 15 Final Rule.

Traditional Medicaid Prescription Drug Coverage

Neither Congress (in 2010) nor CMS (in 2013) wrote on a blank slate when addressing the Medicaid drug coverage issue. In 1990, the Medicaid statute was amended to add a number of drug coverage requirements, including "rebate" provisions. Under those provisions, contained in section 1927 of the Medicaid statute, states were required to cover all "covered outpatient drugs" marketed by manufacturers that signed "national rebate agreements" and paid statutorily-mandated rebates for each drug reimbursed by a state program. 42 U.S.C. § 1396r-8. While states were permitted under the statute to utilize certain "utilization controls" such as prior authorization, Congress established clear limits on the use and implementation of such controls. Further, a detailed scheme for calculating rebates was set out in the statute and subsequent CMS regulation and guidance, including the calculation of rebate amounts, the determination of "best price" for the calculation of innovator product rebate amounts, and exemptions of certain governmental program prices

from the "best price" determination. Until this month, there has never been any guidance as to how the provisions of Section 1927—the drug coverage and rebate provisions—would apply to Section 1937—the ABPs.

The Medicaid Initial Guidance and Proposed Rule

In order to provide states with guidance in creating the new ABP plans for the expansion population, on November 20, 2012, CMS wrote the state Medicaid Directors with initial guidance in how to establish the necessary ABPs in their expansion plans.[7] Recognizing that states needed to understand how to address ABP coverage of prescription drugs, CMS noted:

> Prescription Drugs: Section 1927 of the Act, which describes the conditions for Medicaid coverage of outpatient drugs and the Medicaid drug rebate program, applies to Alternative Benefit Plans. Consistent with this title XIX provision, states have the flexibility to adopt prior authorization and other utilization control measures as well as policies that promote use of generic drugs.
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> All other provisions under title XIX of the Act apply, unless, as described in section 1937, the state can satisfactorily demonstrate that implementing such other provisions would be directly contrary to their ability to implement Alternative Benefit Plans under section 1937. States can use commercial market and/or Medicaid provider qualifications for each benefit. Free choice of qualified providers continues to apply.

Based upon this initial guidance, which was repeated in the January 2013 Proposed Rule,[8] all stakeholders understood that the requirements of Section 1927, including coverage of all prescription drugs subject to a national rebate agreement, would continue to apply to the millions of Medicaid beneficiaries newly covered under the PPACA expansion provisions. That is, that the new section 1937 ABP plans would still be required to comply with all of the section 1927 coverage requirements.

The CMS Final Rule

Unfortunately for beneficiaries and pharmaceutical manufacturers, CMS completely reversed course in the July 15 Final Rule. It limited its prior statements to manufacturer payments of rebates for each drug sold under an ABP plan, but rejected application of the Section 1927 coverage requirements to section 1937 ABP plans. Further, CMS defined the prescription drug EHB to only require coverage consistent with the benchmark plan chosen by the state from the list provided in the statute, and the minimum coverage required for Exchange plans, that is, the inclusion of at least one drug in each therapeutic class.

The Final Rule contains three important provisions relevant to pharmaceutical manufacturers.

First, the Rule defines the scope of prescription drug coverage as that meeting the "essential health benefit" definitions found in 45 C.F.R. § 156.122, which in turn requires coverage to be at least the greater of "one drug in every United States Pharmacopeia (USP) category and class" or the minimum on the state benchmark plan. In other words, Medicaid programs, at least for the expansion population, do not need to provide access to all prescription drugs, but only to the level of coverage contained in a "benchmark" plan, not to fall below one drug per class, which is the definition used for the Exchange plans.

> In developing ABPs, states must include prescription drug coverage consistent with the EHB-benchmark plan standards. These standards are set forth at 45 C.F.R. §156.122 and include the requirement that health plans have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan. We believe such requirements will result in coverage that is similar to the coverage otherwise required under regular Medicaid state plan coverage.

78 Fed. Reg. at 42220. Thus, while CMS permits appeals, it has made clear that the minimum EHB coverage of one drug per therapeutic class is all that need be provided to the newly-enrolled Medicaid beneficiaries.

Second, and far more important, CMS reversed course from its proposed rule and has now opted to eliminate the Section 1927 coverage requirements for the expansion population. The Final Rule now states:

> [T]he amount, duration and scope of coverage for an ABP is determined under section 1937 of the Act, which authorizes benchmark or benchmark-equivalent coverage ''notwithstanding any other provisions that would be directly contrary.'' This being the case, we do not have the authority to require states, when establishing its benefits under its ABP, to meet the coverage requirements of section 1927 of the Act. Doing so would be directly contrary to flexibility with respect to the amount, duration, and scope of coverage provided under section 1937 of the Act. As for the commenters' concerns with the limits provided under section 1927 of the Act as they apply to the Medicaid population, especially on disease specific or chronic care populations, we note that states have considerable discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of prescription drugs covered under ABPs.

78 Fed. Reg. at 42219. Thus, none of the benefits of section 1927 apply, including the coverage requirements.

Third, at the same time, CMS made clear that if a covered outpatient drug subject to a rebate agreement is covered by an APB Plan, then the manufacturer must pay a rebate for each drug reimbursed by a state program. CMS stated:

> To the extent that a prescription drug is within the scope of the ABP benefit as a covered outpatient drug, section 1927 of the Act is then applicable. For such covered outpatient drugs, since payment is available under the state plan, all drug rebate obligations under the rebate agreement are required for drug manufacturers under 1927(b) of the Act. To explain in more detail, the amount, duration, and scope of coverage for an ABP is determined under section 1937 of the Act, which authorizes benchmark or benchmark-equivalent coverage ''notwithstanding any other provision that would be directly contrary.'' But, the drug rebate obligation applies under section 1927 of the Act when payment is made under the Medicaid state plan for covered outpatient drugs as part of the ABP. In addition, to the extent that covered outpatient drugs are within the scope of ABP coverage, the protections and limitations for such coverage under section 1927 of the Act apply. So, for example, to the extent that coverage under an ABP includes a class of covered outpatient drugs, a state could impose limitations on that coverage only consistent with the provisions of section 1927(d) of the Act. In general the requirements for prescription drug coverage under section 1937 of the Act, through the requirement for coverage of EHBs, will mean that ABPs will meet existing section 1927 requirements for Medicaid payment of covered outpatient drugs

78 Fed. Reg. at 42210.

Implications of the Final Rule for Manufacturers:

The CMS Final Rule represents a fundamental shift in drug coverage, at least for the expansion population. From an historical perspective, the new narrow scope of coverage required by CMS represents a fundamental break from the 1990 "agreement" between the industry and the government when Section 1927 was added to the Medicaid statute—that Medicaid would cover all approved drugs so long as the manufacturer signed a national rebate agreement and paid the designated rebate.[9] The Final Rule also represents a retraction from the unwritten "agreement" between the pharmaceutical industry and the White House around the enactment of PPACA, in which industry committed $800 billion in exchange for expanded markets. And sadly, for beneficiaries, and particularly those with diseases for which drugs are not readily interchangeable (like epilepsy, serious mental illness, or AIDS) it may mean a lack of access to medically necessary mediations.

Looking forward, the Final Rule portends far greater competition, and more aggressive state negotiations for supplemental rebates, for branded (and even generic) drugs to be covered under the new APB formularies. States now have the ability to seek steeper supplemental rebates before even covering any product, much less providing preferential formulary positioning for a product. Although the benchmark plan baselines will vary from state to state, there is little doubt that states will have greater flexibility in building formularies, covering (or not covering) particular products, and negotiating deeper discounts or rebates.

It remains to be seen how aggressively states will pursue restrictive formularies and steep additional rebate demands in light of the high federal funds participation rate for the expansion population. The incentive for state Medicaid programs to deny their citizens coverage of a wide range of drugs within each therapeutic class in exchange for high manufacturer rebate payments may fade when the state considers that it is the federal government that benefits from the rebate payments, and not the state itself.

Manufacturers should consider the implications of this new market structure on existing Medicaid rebate rules. More specifically, it is possible that APB rebates could result in setting new best prices, which could increase manufacturer liability for all Medicaid utilization subject to rebating (fee-for-service, Medicaid Managed Care and APB). While price concessions under the national rebate agreement or a CMS-authorized supplemental rebate agreement are exempt from best price,[10] it is not entirely clear whether APB benchmark coverage can be approved by the Secretary outside of the State Plan process. APB rebates are not "supplemental rebates" as contemplated in §1927, and the reach of the best price exemption to these price concessions is unclear. If APB coverage must be the subject of a State Plan Amendment, then the risk of setting a new best price may fall away. On the other hand, if CMS chooses a simple approval process outside of a State Plan amendment, the risk remains. This may be either a sword or a shield for manufacturers, in the sense of either creating risk in negotiating new discounts or rebates that may have broader rebate impacts, or in using existing best price levels as the floor for any negotiations with ABP plans.

Conclusion

In 2010, PPACA's Medicaid expansion held much promise for pharmaceutical manufacturers. In exchange for agreeing to increased Medicaid rebate liability (increased minimum rebate percentages, dramatic redefinition of AMP to increase rebates), manufacturers were anticipating millions more covered Medicaid lives who would, for the first time, be able to access prescription drugs. Unfortunately, as a result of the 2012 Supreme Court decision, and now this EHB Final Rule, that promise appears to be evaporating. Under the new regulations, the expansion population will only have access to

those drugs covered under a restrictive state benchmark plan, at its worst requiring coverage of only one drug per therapeutic class. In requiring such limited coverage, the Final Rule invites states to adopt highly restrictive formularies and to force manufacturers to compete for coverage (and to pay national rebates as well). It remains to be seen whether states will recognize the value of patient access to choice within therapeutic classes, and offer broader formularies for the expansion population than the bare minimums required under the Final Rule. Even if states choose to do so, there may be an additional cost for manufacturers in the form of deeper discounts and rebates.

Manufacturers will need to vigorously monitor formulary developments in the states through the new Alternative Benefits Plans. Manufacturers will also need to consider how further price negotiations with the ABPs may impact "best price" calculations, and other pricing benchmarks. What is clear already, however, is that Medicaid expansion likely will not deliver what was promised in 2010.

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[1] Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; Final Rule and Enrollment; Final Rule; 78 Fed. Reg. 42160, 42194 (July 15, 2013).
[2] http://kff.org/health-reform/fact-sheet/who-benefits-from-the-aca-medicaid-expansion/
[3] http://www.advisory.com/Daily-Briefing/Resources/Primers/MedicaidMap
[4]These benchmark standards have been, and will remain, minimum standards, and states will be allowed to provide broader coverage as they see fit. Certain patient groups, such as the aged, blind and disabled population, are exempted from the 1937 flexibility authority.
[5] www.nga.org/files/live/sites/.../1204POPULATIONEDWARDS.PPTX
[6] The other EHBs include ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. These same ten categories are also required to be covered by the so-called "Exchange" plans and within non-grandfathered employer based coverage.
[7] http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf
[8] Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 Fed. Reg. 4594 (Jan. 22, 2013).

[9] Historically a 15.1% minimum rebate for innovator products, now 23.1% for most innovator products, plus additional CPI-U rebates.
[10] 42 C.F.R. §447.505(d)(6). The statute exempts rebates "under this section:" 1927. It is unclear if rebates paid under section 1937 would have the same best price exemption.