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CMCS Informational Bulletin

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SUBJECT: Beneficiary Protections and Medicaid Drug Coverage - Under Value Based Purchasing (VBP) and Other Innovative Payment Arrangements

The purpose of this Center for Medicaid and CHIP Services (CMCS) Informational Bulletin (CIB) is to remind states and stakeholders of existing federal beneficiary protections that help ensure appropriate beneficiary access to prescription medications, especially as state programs and stakeholders continue to negotiate novel payment arrangements with drug manufacturers.

The Centers for Medicare & Medicaid Services (CMS) understand the challenges that states face managing pharmacy costs, especially as new, innovative gene and cell therapies are brought to market. We are taking several steps to help states meet these challenges. We have approved 13 state plan amendments (SPAs) that authorize states to negotiate with manufacturers for value-based supplemental rebates for a drug, and several more states' SPAs are under review. Moreover, we are issuing this CIB to coincide with the start of the new flexibilities that allow manufacturers to report to the agency multiple best prices for a drug that are connected to a VBP arrangement (as defined at 42 CFR 447.502) and made available to all states. These VBP arrangements will hold manufacturers more accountable for the clinical outcomes of their drugs, while giving more states the opportunity to earn additional rebates depending on how a drug works for patients. In addition, we look forward to working with states through a learning collaborative that will be launched in the fall of 2022 to help states better manage their pharmacy costs, especially for these high cost drugs. We hope this work will lead to productive negotiations between states and manufacturers regarding the cost of these drugs for Medicaid beneficiaries.

Introduction

Alternative VBP arrangements for drugs, such as outcomes-based models and supplemental rebate agreements, have become more commonplace. These arrangements allow state Medicaid agencies to receive additional discounts or rebates from manufacturers on a drug when a drug does not meet certain observed or expected therapeutic or clinical values in a select population, based on applicable evidence-based or outcomes-based measures. As a result of these new payment arrangements, we believe it is important that beneficiaries, states, and manufacturers understand the beneficiary protections currently in

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

place to ensure access to medications under both traditional pharmacy programs and alternative payment arrangements.

In the December 31, 2020 issue of the *Federal Register*, the CMS published the final rule entitled: *Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements* (hereinafter referred to as the December 2020 final rule) (85 Fed. Reg. 87000; CMS 2482-F2). This new regulation permits manufacturers to report multiple best prices for a covered outpatient drug in certain cases. More specifically, it provides that if a manufacturer offers a VBP arrangement to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that VBP arrangement. These arrangements offered by manufacturers to states must meet the definition of a VBP arrangement as specified in 42 CFR § 447.502 and allow the state to collect additional rebates based on a patient's outcomes beyond those that the state will already receive under the Medicaid Drug Rebate Program (MDRP).

We note that states are not required to participate in these VBP arrangements in order for manufacturers to report multiple best prices. In addition to the states' voluntary participation in commercially-available VBP arrangements, states have also been actively negotiating other types of payment arrangements with manufacturers, such as through CMS-authorized supplemental rebate agreements, pay-over-time models, and "subscription" model arrangements under which the manufacturer charges a payer a fixed amount for an unlimited supply of a drug (resulting in a lower per unit price as utilization of the drug increases). Regardless of the type of arrangement, CMS is providing this guidance to ensure that stakeholders are aware of laws and regulations regarding beneficiaries' access to medically necessary medications.

Medicaid Requirements that Protect Beneficiary Access to Drugs

CMS believes it is important to reiterate to states and manufacturers the current federal protections that are in place under the Medicaid program to help ensure appropriate beneficiary access to drugs. States must generally apply these existing broad statutory requirements to Medicaid coverage of prescription drugs, regardless of any type of payment arrangement the state may have with manufacturers, unless an exception applies, such as a waiver.

1. States must cover all covered outpatient drugs subject to a rebate agreement with the Secretary: States must cover all covered outpatient drugs of a manufacturer that has entered into and has in effect a Medicaid drug rebate agreement, and may only restrict or exclude coverage of drugs as expressly described in section 1927(d) of the Social Security Act (the Act). Subject to these permissible restrictions, covered outpatient drugs that are prescribed for a medically accepted indication must be covered. States are permitted to subject any drug to prior authorization as long as it meets the requirements of section 1927(d)(5).

Section 1927(d)(1)(B) of the Act permits states to restrict or exclude coverage of a covered outpatient drug only if the prescribed use is not for a medically accepted indication, the drug is included in the list of drugs or drug classes (or their medical uses) that may be excluded or otherwise restricted by the state (e.g., agents when used for cosmetic purposes or to promote fertility), the drug is subject to restrictions

pursuant to an authorized agreement between the manufacturer and state under a permissible prior authorization program or formulary, or pursuant to a state established formulary that is consistent with federal law.

Section 1927(d)(6) permits states to impose limitations with respect to all such drugs in a therapeutic class, on minimum or maximum quantities per prescription or on the number of refills, if such limitations discourage waste, and may address instances of fraud and abuse. The statute also further provides an enumerated list of non-excludable drugs, classes of drug, or their medical uses at section 1927(d)(7), which a state may not exclude from coverage. In summary, a state must ensure the covered outpatient drugs of a manufacturer with an effective Medicaid drug rebate agreement are covered and available when the covered outpatient drug is prescribed for a medically accepted indication, unless certain exclusions or restrictions apply.

2. State Alternative Benefit Plans (ABP) must follow Essential Health Benefit (EHB) standards when providing prescription drug coverage: When providing coverage under alternative benefit plans to a Medicaid population, states are required to provide prescription drug coverage that meets certain specific drug formulary standards, and to have a process in place such that the Medicaid beneficiary can access clinically appropriate drugs not covered on the state's drug formulary. Specifically, under 42 CFR § 440.347(a)(6), states must provide prescription drug coverage that meets the Essential Health Benefits (EHB) standards described in 45 CFR § 156.122, including a formulary that meets the standards at 45 CFR § 156.122(a), and that includes a process in place that allows the Medicaid beneficiary (or their designee) to request and gain access to clinically appropriate drugs not otherwise covered by the formulary consistent with the EHB standard at 45 CFR § 156.122(c). As specified at 42 CFR § 440.347(e), EHBs cannot be based on a benefit design or implementation of a benefit design that discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health conditions.
3. States generally cannot limit beneficiary access to certain providers because of a specific payment arrangement: In general, section 1902(a)(23)(A) of the Act and 42 CFR § 431.51(b) require that any Medicaid beneficiary may obtain Medicaid services (including covered outpatient drugs) from any institution, agency, pharmacy, person, or organization that is qualified to furnish the service or services, and willing to furnish them to that particular beneficiary. CMS can waive this requirement under section 1915(b) or section 1115 of the Act, and this requirement also would not generally apply under state plan Medicaid managed care programs. Therefore, unless this requirement has been waived, is not applicable, or an exception applies, a state may not limit coverage of drugs to those obtained from a limited list of Medicaid providers or pharmacies. Additionally, under certain circumstances specified in 42 CFR § 431.52, states are required to cover Medicaid services provided out of state to their residents who are Medicaid beneficiaries and who are absent from the state.
4. States generally must comply with the Medicaid comparability requirement: Unless an exception applies or this requirement is waived under section 1115 of the Act, section 1902(a)(10)(B) of the Act and 42 CFR § 440.240 require states to ensure that the services available to any categorically needy beneficiary under the Medicaid state plan are not less in amount, duration, and scope than those services available to a medically needy beneficiary. Also, unless an exception applies or the requirement is waived, these provisions require states to ensure that the services available to any

individual in the following groups are equal in amount, duration, and scope for all beneficiaries within the group: (1) the categorically needy; and (2) a covered medically needy group. Therefore, any payment arrangement a state enters into must result in compliance with these comparability requirements, unless an exception applies or the requirements have been waived.

5. States must adhere to Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirements: Under section 1905(a)(4)(B) and (r) of the Act, states are required to cover all medically necessary services described in section 1905(a) of the Act for children under the age of 21 who are eligible for EPSDT, including prescribed drugs, regardless of any payment arrangement. What this means is that any prescribed drug covered under Medicaid EPSDT requirements is eligible for federal financial participation (FFP), regardless of the applicability of section 1927. In other words, even if the drug is not a covered outpatient drug in accordance with section 1927(k)(2) of the Act or the drug is a covered outpatient drug and a manufacturer does not have in effect a drug rebate agreement, the drug is covered under Medicaid and is eligible for FFP if prescribed under EPSDT requirements.
6. States must continue to have Drug Utilization Review (DUR) Programs in place: As required under section 1927(g) of the Act, a state must continue to have a DUR program targeted, in part, at reducing abuse and misuse of outpatient prescription drugs covered under the state's Medicaid program. The DUR program operates to help ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results for Medicaid beneficiaries. Each state DUR program must consist of prospective drug use review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities. States must continue to apply DUR requirements to covered outpatient drugs regardless of how the state pays for the drug.

Other Federal Laws and Regulations Protecting Medicaid Beneficiaries

There are other federal laws and regulations that states and manufacturers must review and follow in addition to the specific Medicaid statutory and regulatory requirements discussed above. Below, we identify some federal laws that provide additional protection to beneficiaries that states and manufacturers should remain mindful of as they pursue any payment arrangement, however, this does not constitute an exhaustive list of all applicable federal laws and regulations.

1. All parties must comply with the federal fraud and abuse laws: For example, federal anti-kickback provisions at section 1128B(b) of the Act makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a federal health care program. The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a federal health care program. For purposes of the federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The federal anti-kickback statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a federal health care program. The Office of Inspector General (OIG), Department of Health and Human Services (HHS) has promulgated certain

safe harbors potentially applicable to certain value based arrangements, *see, e.g., Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*

(<https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf>). In addition, parties may request an advisory opinion¹ from HHS-OIG regarding the application of HHS-OIG's fraud and abuse authorities, including those related to the federal anti-kickback statute, to the party's existing or proposed arrangement.

2. **States must comply with federal civil rights laws:** Civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex (including pregnancy, sexual orientation and gender identity), age, and disability continue to apply when states participate in any payment arrangement. These laws include Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116 (race, color, national origin, sex (including pregnancy, sexual orientation and gender identity), age, and disability in health programs and activities), Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. §§ 1681 *et seq.* (sex (including pregnancy, sexual orientation, and gender identity) in education programs and activities), the Age Discrimination Act of 1975, 42 U.S.C. §§ 6101 *et seq.* (age), Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (disability), and the Americans with Disabilities Act, 42 U.S.C. §§ 12101 *et seq.* (disability). In accordance with these legal obligations, we noted in the December 2020 rule (85 FR 87014) that manufacturers and payers, including state Medicaid agencies, may not make use of measures that would unlawfully discriminate on the basis of disability or age, among other bases, when designing or participating in VBP arrangements. We further noted at 85 FR 87016, that VBP measures should not endanger certain patients, providers, or impede access to other available medications and treatments, or interfere with the practice of medicine generally.
3. **States must comply with applicable privacy and security laws:** Privacy and security laws and regulations, such as those under the Health Insurance Portability and Accountability Act of 1996 (HIPAA; P.L. 104-191), must be considered when states participate in arrangements that require reporting and recording of patient-specific outcomes data for evaluation to determine payment when payment is tied to outcomes. This is especially important with respect to lower-utilized drugs when disclosure of individually identifiable health information may lead to privacy concerns. Such information should only be used or disclosed in accordance with applicable privacy and security laws, which may limit use or disclosure to the minimum necessary data.

Available Enforcement Mechanisms for CMS

If CMS becomes aware of potential state compliance concerns related to the specific Medicaid requirements discussed above, CMS will first work with the state to help its Medicaid program come into compliance with the applicable laws and regulations. As a next step, when necessary, CMS may review state and local administration of Medicaid programs through an analysis of the state's policies and procedures, on-site review of selected aspects of agency operations, and examination of samples of

¹ [Advisory Opinion Process | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services \(hhs.gov\)](#)

individual case records, in accordance with 42 CFR § 430.32. If these reviews reveal serious problems with respect to state compliance with any federal requirement, or with the state's approved state plan, CMS will request the state to correct its practice. After CMS provides a *notice of non-compliance*, with a request to the state to develop a corrective action plan, if the state fails to comply after being notified and given an opportunity for a hearing, CMS may withhold FFP for non-compliance. The withholding may continue until CMS is satisfied that the state's practices are in compliance with federal requirements (see 42 CFR § 430.35).

CMS does not enforce the non-Medicaid related federal requirements summarized above and will work with the HHS-OIG or the HHS Office for Civil Rights if we believe there are potential compliance issues. CMS may also refer any findings specific to manufacturer drug pricing and drug product related reporting activity to the HHS-OIG.

Conclusion

CMS' policy goal with respect to the MDRP, and state adoption of manufacturers' VBP arrangements, as well as participation in other novel payment arrangements, is to further increase access to high cost therapies for underserved populations, and reduce health disparities. This bulletin reminds states that choose to enter into these arrangements of the range of federally-based protections available to Medicaid beneficiaries. CMS will continue to monitor state Medicaid drug coverage under such arrangements to ensure it remains consistent with the Medicaid statutory and regulatory requirements and that Medicaid beneficiaries can access all medically necessary prescription medications.

For further information regarding this CIB, you may contact John M. Coster, Director of the Division of Pharmacy, at John.Coster@cms.hhs.gov.