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Client Alert

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New Risks, New Rewards, New Exposure

Value-Based Purchasing, Multiple Best Prices, Expanded Alternative URA, and other MDRP Drug Pricing Changes in Proposed Rule

On June 17, 2020, the Centers for Medicare & Medicaid Services ("CMS") released a major proposed rule ("Proposed Rule") in a bid to update and expand key regulations governing the Medicaid Drug Rebate Program ("MDRP"). If finalized as written, these changes will impact manufacturers' commercial strategies, government payor program liabilities, lifecycle management plans, patient assistance regimes, and other important considerations.

The Proposed Rule contains a major new proposal to empower value-based purchasing ("VBP") arrangements between manufacturers and commercial insurers by liberalizing the MDRP Best Price rules, including through the submission and utilization of multiple Best Prices for a single drug in a single quarter While the VBP proposal immediately captured the headlines, CMS also proposes to dramatically increase the number of drugs subject to what is known as the "alternative URA" calculation. If finalized, this could result in a substantial expansion of Medicaid rebate liability and 340B exposure for pharmaceutical manufacturers of innovator oral solid drugs. The VBP and alternative URA proposals, along with other changes contemplated by CMS, are analyzed in detail below.[1]

To aid analysis, we have prepared a redline of the proposed changes against the current Medicaid regulations, available **here**.

We at King & Spalding stand ready to help you understand and interpret the Proposed Rule, and to apply it to your portfolio and practices. We look forward to helping clients draft and submit formal comments in response to the government's proposals.

Comments are due no later than 5 pm on July 20, 2020.

1. Value-Based Purchasing Arrangements Best Price Proposal

Over the past decade, drug manufacturers and payors (both public and commercial) have expressed great interest in value-based reimbursement arrangements under which payment for a prescription drug or biologic could vary depending on its outcome in a particular patient. Several state Medicaid programs—including Oklahoma, Michigan, Colorado, Louisiana, and Massachusetts—have entered into VBP contracts with drug manufacturers in recent years.

While VBP arrangements for very high cost, potentially curative gene therapies, and certain orphan drug therapies has captured media, industry, and Congressional attention,[2] manufacturers have also pursued VBP arrangements with commercial payers for numerous other products.[3] Public payor arrangements have been important advances in value-based contracting, but they have been the exception rather than the norm. Manufacturers' concerns about establishing an unsustainably low Best Price (e.g., if a drug is not successful in a given patient), or running afoul of the Anti-Kickback Statute (by either offering certain discounts that are not passed through to all federal health care programs or by offering incentives for uses on potentially less qualified patients), has hindered more widespread adoption of VBP arrangements in the commercial markets.

CMS acknowledged the importance of VBP arrangements in the preamble to its February 2016 MDRP final rule.[4] It issued program notices to state Medicaid programs and manufacturers on July 14, 2016 encouraging stakeholders to bring specific proposals to the government for consideration.[5] For the first time, the Proposed Rule contains specific direction from CMS regarding how VBP arrangements could be addressed in the determination of Best Price.

Importantly, the Proposed Rule does not address the potential fraud and abuse challenges for VBP arrangements that currently inhibit their use. Instead, CMS merely notes that its VBP arrangements proposal is not intended to "contradict any OIG guidance," and, during its June 19, 2020, open door conference call on the Proposed Rule, invited written comments on anti-kickback considerations. Of course, in October 2019, OIG expressed concerns about the use of VBP arrangements with respect to drugs and certain devices and opted not to offer protections for such arrangements without further comment and consideration.[6] Accordingly, the Proposed Rule only addresses part of the outstanding concerns about VBP and leaves the remaining issues to be addressed at a future time (if at all).

Specifically, CMS proposes to define a VBP arrangement as:

> an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):
>
> - Evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product;
> - Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses. (PR at 37292)

In setting out this definition, CMS accepts as indicia of value, "the absence of disease over a period of time, reducing a patient's medical spending, or improving a patient's activities of daily living thus resulting in reduced nonmedical spending" (id.). CMS does not specifically tie these factors to the clinical trial results for a particular drug or biologic, and appears to permit value-based metrics that go beyond the label indication of a product. CMS also invites

comments on how to interpret the concept of "substantially" in the definition, namely, how much of a product's price must be tied to the outcome.

CMS proposes two different methodologies by which manufacturers can accommodate VBP arrangements in the Best Price determination: (1) as a bundled sale, and (2) using multiple Best Prices. Under the bundled sale methodology, which is currently commonly used in this and other contexts, the discount resulting from a performance-based 'failure' in a VBP arrangement is "distributed proportionally to the total dollar value of the units of all the drugs sold in the bundled arrangement" so as not to "reset the manufacturer's best price based upon the ultimate price of one unit of a drug" (id.).

The second proposed methodology—multiple Best Prices for a single NDC-9—is an entirely new concept to government price reporting. CMS proposes that "a single drug may be available at multiple price points, each of which may establish a 'best price' based on the relevant or applicable VBP arrangement and patient evidence-based or outcome based measures" (PR at 37293).[7] CMS explains: "under VBP, the manufacturer would report a single best price for the drug for the quarter for sales of the drug in that quarter. In addition, the manufacturer would also report a distinct set of 'best prices' that would be available based on the range of evidence-based or outcomes measures for that drug that are possible under the VBP arrangement" (PR at 37293).

CMS openly acknowledges the difficulties it will encounter operationalizing this concept, which will undoubtedly pose significant price reporting challenges for manufacturers utilizing VBP arrangements. If those issues can be successfully navigated, however, VBP arrangements with commercial manufacturers may no longer be inhibited due to Best Price considerations.[8]

The hope appears to be that state Medicaid programs would be able to access the terms of all VBP arrangements that manufacturers negotiate with commercial insurers, either universally or on a patient-by-patient basis. It is unclear, however, how a state would determine which Medicaid beneficiaries would be subject to the VBP arrangements and which would remain in the standard fee for medication agreements that exist today (subject to statutory rebates).[9] States that choose to enroll beneficiaries in VBP arrangements may also be subject to significant obligations, including the requirement to monitor health outcomes or measure cost savings.

The Proposed Rule fails to address a number of important issues with regard to its VBP solution:

First, as indicated above, it does not address whether and to what extent VBP arrangements fit within the limits of the federal Anti-Kickback Statute ("AKS"). For example, VBP pricing does not fall within the four corners of any existing safe harbor or exceptions under the AKS, and the U.S. Department of Health and Human Services Office of Inspector General ("OIG") may view these arrangements as an improper inducement to stimulate utilization. Similarly, follow-up testing and evaluation of medication health impacts may be an unlawful inducement if not appropriately structured. Accordingly, at a minimum, if finalized, the Proposed Rule would need to be aligned with some type of new OIG proposal on protections for VBP arrangements for drugs.

Second, while the Proposed Rule addresses how Best Price could be determined and submitted (however obliquely), the proposal is unclear as to how VBP concessions will impact ceiling prices under the 340B Drug Discount Program.[10] Whether there will be multiple 340B ceiling prices for each drug based on differing Unit Rebate Amounts is not discussed. Which 340B patients will be entitled to which prices goes unexplored. Furthermore, the timing of Best Price statement and revision has the potential to be highly problematic for Covered Entities and manufacturers alike. CMS will need to clarify these issues so that potential impact on the 340B Program does not hinder adoption of VBP arrangements.

Third, because the Proposed Rule pertains to Medicaid pricing considerations only, the impact on Medicare Part B drugs, and the calculation of Average Sales Price ("ASP"), is not addressed. To date, CMS has not explained how VBP arrangements could work in the context of Part B. We await further guidance or rulemaking from CMS on these issues, including whether CMS would allow for separate ASPs for individual patients in Medicare Part B VBP arrangements.

Fourth, the Proposed Rule addresses VBP arrangements tied to performance of a particular product, but fails to address a second and common form of VBP agreements, known as "payment over time" arrangements. Under these arrangements, a manufacturer agrees to accept payment over a period of several years unrelated to the outcome of a particular drug in a particular patient. Some manufacturers have already entered into such arrangements through selling the product to a specialty pharmacy, and having the specialty pharmacy serve as the "bank" and offering the payment over time terms to payors,[11] and for that reason CMS may have chosen not to address the issue. These arrangements, however, will continue to be utilized in practice, and CMS will need to address them squarely.

Finally, CMS also has not addressed a critical issue in long-term value-based contracts that Congress has attempted to address in pending legislation— "portability"—which is the question of what happens when a patient changes plans, or moves in or out of Medicaid coverage. This issue will need to be addressed by CMS or navigated by contracting parties when entering into VBP arrangements.

2. New Formulations and the Alternative URA

If the VBP proposals described above are of critical importance to specialty drug manufacturers, CMS's proposals regarding the appropriate reach of the "alternative URA" are nothing less than stunning to manufacturers of oral solid drugs.

Manufacturers of certain follow-on oral solid dosage form drugs have been subject to an alternative URA calculation since 2010.[12] That mechanism ties new products' rebate obligations to the inflation penalty obligations of predecessor products, and in so doing has the potential to significantly increase manufacturer Medicaid rebate liability (and 340B exposure).

CMS proposes to very dramatically increase the universe of products subject to the alternative URA calculation by creating an entirely new definition of "new formulation" (PR at 37294), and by revising the definition of "oral solid dosage form" (PR at 37296). These changes may be the most consequential reinterpretations of law in the Proposed Rule for small molecule drug manufacturers.

CMS proposes to include in the definition of a "new formulation" "any change to the drug, provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug" (emphasis added). Examples of products that would be new formulations under the proposed definition include:

- Extended release formulations;
- Changes in dosage form, strength, route of administration, ingredients, pharmacodynamics, or pharmacokinetic properties;
- Changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC); and

- Combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device.

This proposal is a vastly broader conception of "new formulation" than is currently understood. If this proposal is adopted, every new strength of an oral solid drug would constitute a line extension subject to the alternative URA, as would new products that share but one active ingredient with an existing oral solid drug. Currently, approval of a new strength provides the basis for an independent price reporting stream (PR at 37295). CMS' proposal would effectively tie inflation penalty rebate liability across strengths by operation of the alternative URA requirement. Similarly, rebate liability for a new product with a new indication—apparently even if it has a separate NDA—could be tied to a preexisting product's inflation penalty rebate under this definition. Treatment of combination drugs under this proposal raise very significant operational questions.

In another bid to increase the reach of the alternative URA, CMS proposes to require that only the initial brand name drug—and not the new formulation—be an oral solid for the alternative URA calculation to apply (PR at 37294). This change, particularly in combination with the expanded definition of new formulation, could expose non-oral solid line extensions (previously exempt from the alternative URA calculation) to increased rebate liability.

The Proposed Rule seeks to expand the definition of "oral solid dosage form" to include not just "tablet, capsules, or similar drug products intended for oral use," as currently defined, but any product that is orally administered "that is not a liquid or gas at the time the drug enters the oral cavity" (PR at 37296). The effect of this proposal would be to include products like sublingual films, and even orally inhaled powdered drugs, in the set of initial brand name drugs that could give rise to "new formulations."

CMS' proposed changes to the definitions of "new formulation" and "oral solid dosage form" would expand the universe of products subject to the alternative URA, and could result in very significant additional rebate liability and 340B exposure for manufacturers of oral solid drugs. This is particularly true given that in 2018 Congress amended Section 1927 of the Social Security Act to change the way the "alternative URA" is calculated by making the "alternative" rebate additive, rather than substitutional, and therefore much more expensive for the manufacturer.[13]

3. CMS-Authorized State Supplemental Rebate Agreements

Medicaid rebates paid by manufacturers—both federal and "CMS-authorized supplemental" rebates—are specifically excluded by from standard AMP, 5i AMP, and Best Price. These regulatory exclusions were straightforward when only Medicaid fee-for-service utilization was subject to rebates.

Since the Affordable Care Act in 2010, however, Medicaid managed care organization ("MCO") utilization has been rebatable. Over the last decade, some states have permitted supplemental rebates to be (a) negotiated by, and/or (b) paid to, Medicaid MCOs. This outsourcing of supplemental rebate negotiation and payment to commercial organizations troubles CMS.

The Proposed Rule seeks to create a definition of "CMS-authorized supplemental rebate agreement" that would permit only those supplemental rebate dollars (a) paid under a state plan amendment-approved agreement, and (b) paid to a state Medicaid program, to be excluded from 5i AMP and Best Price (presumably the rebates would be excluded from standard AMP on RCP grounds). Notably, this interpretation appears to be inconsistent with the broad statutory requirement that "rebates under … section [1927 of the Social Security Act]" are excluded from Best Price.[14] Stakeholders should consider submitting comments asking whether this proposed change is an appropriate narrowing of the broad statutory exclusion. In any event, this clarification may change the rebate

negotiation calculus for some manufacturers, and perhaps cause some states to re-think their relationships with Medicaid MCOs.

4. Patient Assistance Program Exclusions and PBM Accumulator Programs

In what will surely cause a stir in the ongoing PBM-plan-patient-manufacturer tussle over copay assistance programs, CMS proposes to shift the burden of demonstrating that the full value patient assistance dollars goes to patients before they can be excluded from Best Price (and AMP) (PR at 37299). Currently, many manufacturers reasonably assume that their PAP funds benefit the patient; the Proposed Rule would require that a manufacturer affirmatively "ensures" so.

The genesis of this concern is the advent of PBM/plan "accumulator" programs. Under these arrangements, the value of certain assistance, while paid by the manufacturer on behalf of the patient (usually to a dispensary to offset copayment obligations), is circumvented by the plan and its value is denied to the patient, ostensibly as a cost control measure. The Proposed Rule provides helpful examples of the operation of these programs (PR at 37298). CMS believes that manufacturers do not sufficiently "monitor or place parameters around how the benefits of their manufacturer sponsored assistance programs are applied" (PR at 37299). Therefore, CMS proposes to strip the Best Price exception for patient assistance from any manufacturer that does not "ensure" that the assistance is not subject to an accumulator or similar mechanism.

CMS does not go so far as to suggest—as some enforcement officials have done—that accumulator programs are intentional, collusive agreements between manufacturers and PBMs/payors to circumvent Best Price while sending undisclosed discounts to plans. Rather, CMS proposes to place on manufacturers an affirmative burden to "ensure" that their patient assistance programs are not undermined and leached by these entities. Stakeholders should consider submitting comments regarding the degree to which manufacturers would be forced to obtain visibility into/management of others' commercial plan coverage structures in order to provide copayment assistance to patients, and whether and to what extent doing would be practically possible or desirable.

5. Authorized Generics and Standard AMP

The Proposed Rule seeks to integrate into the MDRP regulations changes made to the treatment of authorized generic sales in standard AMP by the Health Extenders Act in 2019 (and recently interpreted by CMS in Manufacturer Releases Nos. 111 and 112).[15]

In short, CMS proposes to amend the regulatory definition of "wholesaler" to exclude reference to "manufacturers;" to remove "sales to other manufacturers who act as wholesalers" from the list of standard AMP eligible sales; and to revise the definition of "authorized generic drugs" to align with the treatment described in Manufacturer Release Nos. 111 and 112 cited above. Note that CMS specifically proposes that these changes be applicable retroactively to the fourth quarter of 2019.

The proposed changes to the existing regulatory definition of "authorized generic drugs" would require that AMPs be calculated separately for a primary manufacturer's drug and the authorized generic. The AMP of the "brand" drug (a slightly misleading term given the recent drug classification changes) would exclude both (a) transfer sales to the secondary manufacturer, and (b) any sales out of the secondary manufacturer (as is currently the case). Importantly, this directive would apply whether the secondary manufacturer is independent of the primary manufacturer, an affiliated entity, or the very same manufacturer (PR at 37300).

As an aside, it is unclear how manufacturers are to reconcile this proposed prohibition on AMP blending of authorized generic sales within a company, on the one hand, with guidance issued by CMS in 2016 that permits blending the AMPs of two NDC-9s that are the same when sold by a single manufacturer, on the other.[16] The question of one AMP (blending) or two (no blending) appears to turn on whether the pair of NDC-9s includes an authorized generic. If one product is an authorized generic, Manufacturer Release No. 112 would dictate two separate AMPs. If neither of the products are authorized generics, CMS' July 2016 guidance states that a manufacturer may choose to blend or submit separate AMPs.

Unfortunately, the regulatory definition of 'authorized generic' at 42 C.F.R. § 447.502 is so broad as to define almost any 'second' drug sold under a different labeler/package code to be an authorized generic—"any drug … that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging … than the brand name drug." Under this definition, for example, divested inventory could be an authorized generic for the acquiring manufacturer, as could the same dosage form and strength of a drug being sold under a different trade name, or with slightly different packaging. Blending in these clearly non-authorized generic contexts arguably should not be prohibited, but the overbroad definition of "authorized generic" may compel it.

CMS' proposed change to the regulatory definition of "authorized generic drugs" does not address what is and is not an authorized generic, just what to do with one once it is identified. Stakeholders should consider taking advantage of this opportunity to comment on the definition of authorized generic drugs, and to suggest that it track more closely what an 'authorized generic' really is for practical purposes.

6. Other Proposals to Align Regulations with Statutory Language

As discussed in detail in our April 22, 2019 Client Alert,[17] Congress recently amended the MDRP statute to address drug misclassification in the Medicaid program. CMS seeks to amend the existing regulatory definitions of "innovator multiple source drug" (PR at 37294), "multiple source drug" (PR at 37296), and "single source drug" (PR at 37297) in the Proposed Rule to align with the statutory definitions.

Prior to 2015, noninnovator ("N") drugs were subject only to basic Medicaid rebates at 13% of AMP. In 2015, Congress revised the MDRP statute (effective 1Q 2017) to require that manufacturers calculate and pay both basic and additional ("inflation penalty") rebates on N drugs. While the method of determination of base date AMP for N drugs is different than it is for innovator ("S" or "I") drugs,[18] the inflation penalty provisions now operate in the same way for all covered outpatient drugs. The 2015 amendments also applied the 100% of AMP cap on URA to N drugs for the first time. The Proposed Rule seeks to codify the 2015 changes in the MDRP regulations in 42 C.F.R. § 447.509(a), "Medicaid Drug Rebates" (PR at 37300). The proposed regulatory language does not deviate from the substance of the MDRP statute, creating an additional rebate calculation provision for N drugs at 42 § 447.509(a)(7) that parallels the additional rebate calculation provision for S/I drugs at § 447.509(a)(2).

7. State Submissions of Drug Utilization Data

State Medicaid programs are required to submit accurate and up-to-date reports to CMS reflecting the reimbursed unit data for which they have sought rebates from manufacturers. These reports are known as "State Drug Utilization Data" reports, or "SDUDs." Apparently, states have been doing a poor job of submitting accurate SDUDs to the federal government. As a result, CMS proposes significant changes to 42 C.F.R. § 447.511 ("Requirements for states") to address these lapses, including new certification requirements that mirror those required of manufacturers for submitted AMP and Best Price data (PR at 37289).

8. Changes to State Medicaid Program Opioid Drug Utilization Review Programs

CMS seeks to make changes to certain state Medicaid Program opioid Drug Utilization Review Programs addressed at 42 C.F.R. Parts 438 and 456 that are beyond the scope of this Client Alert. If you have questions about these particular areas, please contact one of the authors and we will direct you to a King & Spalding subject matter expert.

[1] On June 17, CMS Administrator Seema Verma issued a blog in Health Affairs adding additional insight into the scope of the Proposed Rule. Congress has also addressed the issue generally in Section 208 of the Prescription Drug Pricing Reduction Act of 2019, S.2543, although the legislation does not address Best Price issues directly.

[2] *See, e.g.* Novartis/Avexis launch of Zolgensma; Spark launch of Luxturna.

[3] *See, e.g.,* Cigna announcement of agreements with Amgen and Sanofi/Regeneron for PCSK9 treatments.

[4] Centers for Medicare & Medicaid Services, Final rule with comment period, "Medicaid Program; Covered Outpatient Drugs," 81 Fed. Reg. 5170, 5253 (February 1, 2016), *at* https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf (stating that CMS does "not believe it is necessary that this regulation detail every arrangement that may subsequently adjust the prices available from the manufacturer. With the recent introduction of value-based purchasing arrangements in the pharmaceutical marketplace, we recognize the value of such arrangements especially when they benefit patients. We are also interested in assuring that states and Medicaid programs have clarity as to how these arrangements might exist in Medicaid. Therefore, since these arrangements are unique, we are considering how to provide more specific guidance on this matter, including how such arrangements affect a manufacturer's best price.")

[5] Medicaid Drug Rebate Program Notice for State Technical Contacts, Release No. 176 (July 14, 2016), *at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-176.pdf; Medicaid Drug Rebate Program Notice for Participating Manufacturers, Release No. 99 (July 14, 2016), *at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-099.pdf (together informing states and manufacturers on how to seek guidance from CMS regarding specific VBP arrangements and encouraging states to consider entering into such arrangements as a means to address high cost drug treatments.").

[6] *See* U.S. Department of Health and Human Services, Office of Inspector General; Proposed rule; "Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 84 Fed. Reg. 55,694 (October 17, 2019), *at* https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22027.pdf.

[7] The authority for CMS to propose this methodology is unclear. CMS claims that it can reinterpret its prior Best Price regulation, which set a single Best Price for each "pricing structure," and, since VBP arrangements implicate multiple pricing structures, there can now be multiple

Best Prices (PR at 37293). CMS does not analyze the statutory authority supporting its proposed change, and it is uncertain whether referencing prior rulemakings in this way would provide sufficient support for the new interpretation if it were challenged in court as *ultra vires.*

[8] As indicated above, potential fraud and abuse risks may still remain.

[9] Nor is it clear how states will be able to enroll some, but not all, beneficiaries in such arrangements, given the MDRP statute's requirement that all beneficiaries receive the same benefit as measured in "amount, duration and scope." Social Security Act § 1396(a)(13).

[10] *See* 42 U.S.C. § 256b. The 340B ceiling price for an innovator drug is a function of a product's AMP and its Unit Rebate Amount, which can be set, in part, by its Best Price. In this respect, the MDRP and 340B travel together.

[11] *See, e.g.*, https://www.novartis.com/news/media-releases/avexis-announces-innovative-zolgensma-gene-therapy-access-programs-us-payers-and-families.

[12] *See* 42 U.S.C. § 1396r-8(c)(2)(C); 42 C.F.R. § 447.509(a)(4).

[13] *See* Medicaid Drug Rebate Program Notice for Participating Manufacturers, Release No. 109 (August 9, 2018), *at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-109.pdf.

[14] 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I).

[15] *See* Medicaid Drug Rebate Program Notice for Participating Manufacturers, Release No. 111 (October 17, 2019), *at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-111.pdf; Medicaid Drug Rebate Program Notice for Participating Manufacturers, Release No. 112 (May 18, 2020), *at* https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-112.pdf.

[16] *See* Centers for Medicare & Medicaid Services, "Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC) Frequently Asked Questions," FAQ 23 (July 6, 2016), *at* https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/FAQ070616.pdf.

[17] *See* King & Spalding Client Alert, "Congress Acts to Eliminate MDRP Misclassification" (April 22, 2020), *at* https://www.kslaw.com/news-and-insights/congress-acts-to-eliminate-mdrp-misclassification.

[18] *See* 42 U.S.C. §1396r-8(c)(3)(C).