

FoCUS

Financing and Reimbursement
of Cures in the US

July 20, 2020

Submitted electronically

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2482-P
P.O. Box 8016,
Baltimore, MD 21244-8016.

Re: [CMS-2482-P] 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

Dear Administrator Verma:

Massachusetts Institute of Technology's NEWDIGS FoCUS project appreciates the opportunity to comment on CMS-2482-P. The Financing and Reimbursement of Cures in the US (FoCUS) Project is a diverse, stakeholder consortium stewarded by the MIT Center for Biomedical Innovation's NEWDIGS Initiative. FoCUS' mission is to collaboratively address the need for new, innovative financing and reimbursement models for durable/potentially curative therapies that ensure patient access and sustainability for all stakeholders. This multi-stakeholder effort has gathered over 90 developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics. In keeping with our academic mission, FoCUS does not seek to advocate, but rather to inform the debate based on the learnings from our cross-sectoral design labs and research efforts.

We applaud the efforts CMS has taken to solicit and respond to feedback particularly toward the proposed rule. We believe the currently proposed rule moves towards enabling value-based payment, to the benefit of patients. We offer five suggestions to further improve value-based payment implementation. Our comments will focus on proposed changes to the Medicaid Drug Rebate Program as prompted by the proposed rule.

Enabling value-based purchasing (VBP) arrangements that allow payers (commercial and Medicaid) and developers to negotiate and facilitate appropriate patient access to durable, potentially curative treatments is desirable. VBP models allow payers and developers to address financing challenges (actuarial risk, payment timing, performance uncertainty – see FoCUS [toolkit for more detail](#)) associated with new cell and gene therapies and support stakeholder alignment on the value of a medicine. If not addressed these uncertainties may reduce or slow patients' access to medicines, as well as the related clinical benefits and any financial benefits to payers in terms of avoidance of more expensive services and hospitalizations. We have confidence in the ability of stakeholders to negotiate better mutual results than the *status quo*.

FoCUS members have been advancing several such precision financing solutions (please see FoCUS [toolkit for more detail](#)):

- **Milestone-based contracts (outcomes-based):** A milestone-based contract helps payers manage potential performance risk associated with a therapy. It assumes an upfront payment by a payer of the agreed-upon price for a medicine. The developer is then contractually obligated to provide a refund for non-performance if specific performance milestones or outcomes are not met. These agreements can be single- or multi-year;
- **Installment contracts (spread payments to help stakeholders manage payment timing risk):** These contracts can be simple payment-over-time contracts or can incorporate a product performance component, which we call a performance-based annuity. A performance-based annuity helps payers manage potential performance risk associated with a therapy and spreads the cost of that therapy over time, thus smoothing payment timing. It reflects that therapy performance is established over a period greater than one year and thus a contract term of greater than one year. By spreading payments over multiple years, it also partially mitigates the actuarial risk of both a surge from patient backlog and rare, but high-cost, cases. This approach might include an up-front payment of some portion of the product cost, as well as a commitment to further payments from the payer every year for a defined number of years, with outyear payments triggered by outcomes being achieved;
- **Subscription contracts:** A subscription model helps payers manage total budgetary cost of a medicine and to some extent actuarial uncertainty for the payer around how many patients might receive a particular therapy by establishing a fixed ceiling for a given year for either a target level or unlimited drug supply. A multi-year subscription can also mitigate the actuarial risk of a surge from patient backlog. It can be structured to help align public health, payer and manufacturer incentives to support increased patient access to medicines; and
- A third-party **Orphan Reinsurer and Benefit Manager (ORBM):** A FoCUS-proposed, new service solution, the ORBM, combines the risk-bearing of reinsurers with the therapy contracting capabilities of pharmacy benefit managers (PBMs), the provider network building and medical management capabilities of insurers, and perhaps a specialty pharmacy distribution capability. These entities can also enable value-based payment models; and
- A **warranty model:** A warranty reimburses payers for other drug and medical costs should the performance risk associated with a therapy be actualized over one or multiple years. Conceptually, a developer would make a product warranty available on a named patient basis to cover expenses and other costs that would have been avoided had the product performed as intended. Operationally, the warranty would be administered by a third-party insurance provider. The policy is issued to the payer and reimburses the policy holder for future expenses incurred due in the event that the covered therapy does not meet the developer's efficacy promise. Warranty payments are thought to represent covered damages as opposed to a rebate associated with the price of the therapy.

Under current Medicaid Best Price reporting requirements, the adoption of these precision financing solutions faces four core calculation challenges:

- **Single patient skew:** The risk that poor outcomes for one payer's single patient could lead to an artificially low Best Price that extends to rebates paid on a nationwide basis in connection with every unit of drug utilized by Medicaid patients, regardless of how well the treatment performed for the individual Medicaid patients.
- **Reconciliation uncertainty for contracts beyond three years:** Price reporting requirements for performance-based contracts and annuities with terms greater than 12 quarters are unclear and so effectively discouraged.
- **First payment distortion:** There is ambiguity with respect to CMS's interpretation of existing regulation regarding AMP and BP reporting requirements. As discussed below, existing regulation could be interpreted to permit developer reporting, under AMP and BP, of the total price to be paid across installment contracts. Yet, in the absence of CMS clarifying that it too has adopted this interpretation,

developers may be discouraged from adopting installment arrangements out of concern that (i) the first payment in an installment model could be construed as the full price and thereby establish a new best price; and/or (ii) AMP could be viewed as needing to be calculated on the basis of the individual installment payments, which would set an artificially low baseline AMP, which cannot be restated for later data. With AMP then increasing over time with subsequent payments, the product could be subject to a significant artificial inflation penalty for price increases that outpace inflation as part of the Medicaid drug rebate calculation.

- **Unit pricing challenge:** Under today's regulations and guidance for calculating Medicaid Best Price, which are grounded in per-unit calculations, a subscription model which negotiates a lump sum amount for a target level of usage, or in the extreme all usage over a period of time results in several challenges, including:
 - Reporting creates the potential for unit price volatility as the number of units utilized might not be consistent across price reporting periods;
 - Capitated agreements or two-part tariff agreements could result in treatments beyond a negotiated number being considered priced at \$0, resulting in a new Best Price for all Medicaid volumes;
 - A lump sum agreement made in a particular context might result in a unit price that would not have been negotiated in a different context - tying subscriptions to unit prices could discourage utilization of a useful approach.

The following table lines up the issues against individual financing solutions. Uncertainties regarding the warranty is raised in point #5 below.

Figure 1: MBP Calculation Issues by Financing Solution

Issue	Milestone-based Contract	Performance-Based Annuity	Subscription Contract	ORBM
Single Patient Skew	X	X		X
Term > 3 years	X	X	X	X
First payment distortion		X		
Unit pricing challenge			X	X

CMS' Proposed Rule takes an important step forward in enabling outcomes-based contracting for Medicaid and commercial payers by addressing several of the calculation issues making precision financing solutions broadly possible – specifically the single patient skew and reconciliation uncertainty for contracts greater than three years. We would encourage CMS to issue a Final Rule this calendar year to enable all stakeholders to benefit from value-based purchasing now as cell and gene therapies are rapidly coming to market, while recognizing a likely need for further sub-regulatory guidance. We ask CMS to further consider modifications, as well as clarifications regarding the interpretation of existing rules, to promote greater use of the full range of precision financing solutions by addressing first payment distortion and unit pricing challenges, as well as to address operational barriers to adoption of precision financing solutions where possible. We also include suggestions on areas where additional regulatory clarification or innovation would be helpful in regards to the

approaches suggested in the Proposed Rule. To encourage growth in value-based purchasing, we anticipate that regulatory room for additional sub-regulatory guidance, as stakeholders gain experience with the framework and specific VBP arrangements are proposed, may be needed.

Specifically, we offer the following suggestions.

1. Our reading of the CMS Proposed Rule suggests that CMS is trying to offer flexibility to allow stakeholders to negotiate mutually acceptable contracts that enhance patient access to medicines, while continuing to ensure that Medicaid receives preferential pricing. **Given the variety of indications potentially treatable by durable cell and gene therapies we believe a diverse set of precision-financing options and designs will be needed to accommodate individual circumstances and to enhance competition. We would encourage CMS to ensure flexibility continues to be a design principle.**

Our experience within FoCUS is that, in addition to unique aspects of certain therapies or diseases, individual payers and developers have different needs, preferences and constraints in contracting and need flexibility to arrive at mutually acceptable solutions. This flexibility extends to the structure of the contract, its duration, the target metrics and the target outcomes, among others. Our FoCUS experience has highlighted the challenges of aligning on an outcomes measure across stakeholders. For rare diseases, which many of the gene therapies in the pipeline are targeting, there is the additional complication of trying to identify the right outcome for a VBP in a rare, progressively debilitating disease with a heterogeneous population.

Based on our reading, we believe CMS intends for State Medicaid organizations to be able to opt into a VBP arrangement on a voluntary basis, including to opt into the requirement to track outcomes, through contracting with a developer, or else to continue with traditional approaches and receive the standard Medicaid statutory rebate. We also believe CMS intends for the use of VBP arrangements and within that a multiple best price point versus a bundled sales approach to be voluntary on the part of manufacturers. *We encourage CMS to confirm this interpretation in the course of finalizing the Proposed Rule.* We believe such diversity and innovation are good for Medicaid, as CMS has established approaches to protect Medicaid in a VBP environment.

2. The proposed rule takes an important step forward in addressing calculation barriers to broader adoption of milestone-based contracts. Yet, **we urge CMS guidance to clarify its interpretation of existing regulatory or statutory requirements relating to Medicaid Best Price and Average Manufacturer Price calculations to support adoption of payment-over-time and subscription models.**

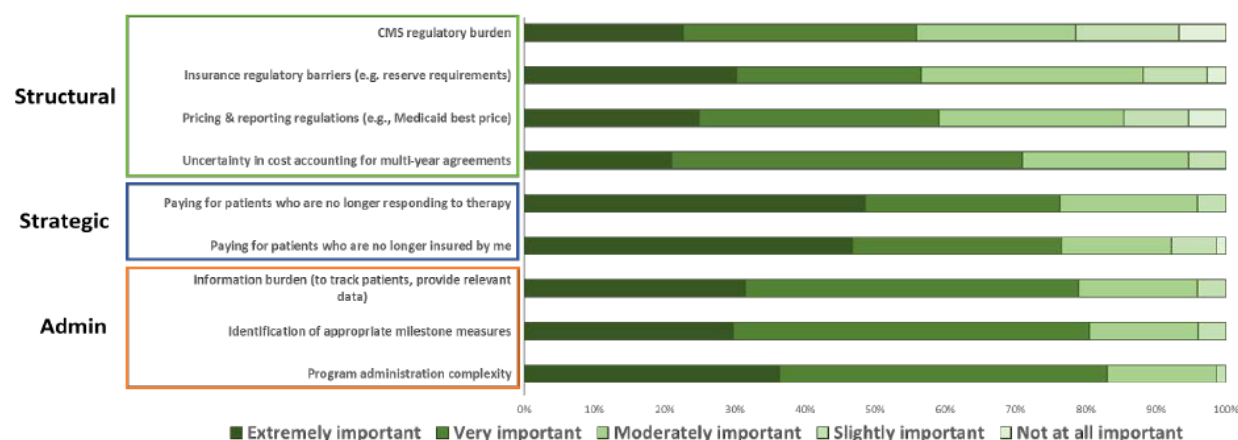
Performance-based annuities and subscription models have been highlighted in FoCUS Design Labs as being of value to address financing challenges associated with durable, potentially curative therapies. *It would be helpful if CMS could clarify its interpretation of existing regulation to thereby provide clear answers to concerns regarding First Payment distortion as well as the Unit Pricing challenges of the subscription model.* One solution for first payment distortion that we believe could be already available to CMS is for the agency to clarify that it interprets AMP and BP as follows: 1) the AMP definition allows a developer to report the total price under the set contract as AMP at the time of sale (instead of reflecting in AMP at the time of sale only the initial payment and then reflecting subsequent payments in AMP when they occur); and 2) in the case of BP, the “price available from the manufacturer” means the total price as the contract is set, inclusive of all installments yet to be paid. Under this interpretation, developers would report the agreed-upon sum of all the payments in the contract as the net price(s) under the contract. *In this case, it would also be helpful if CMS could confirm the reportable*

transaction level for such arrangements (i.e., developer to PBM, not developer to independent PBM clients, etc.). Finally, clarification on how any related financing charges should be treated would be helpful.

3. We would encourage CMS to explore how it could play a role in addressing a broader set of operational barriers to the adoption of value-based contracting

Beyond pricing regulations, FoCUS’ research suggests a significant level of administrative barriers to the adoption of precision-financing solutions, as the figure below illustrates in red. FoCUS conducted an online survey (September 2018-April 2019) of 77 payers, representing 153 commercial fully-insured, Medicaid, Medicare Advantage, and self-insured employer plans.

Figure 2: Payer barriers to alternative financing, by importance (n=77)



In particular, payers highlighted the administrative complexity of establishing and administering such programs, as well as the information burden to track patients. Our Design Lab experiences and conversations suggest that these barriers are particularly high for smaller payers or payers who are new to value-based payment negotiations for medicines. Therefore, we would encourage CMS to consider the following:

Facilitate scaled-up CMS grants to State Medicaid agencies to develop the capabilities and capacity to design, negotiate and implement these agreements. FoCUS experience suggests that there is a meaningful learning curve in establishing these types of value-based payment arrangements. Grants to date have enabled some adoption by States. More will be required to scale.

Consider options for simplifying the process of obtaining approvals to enable adoption of precision financing solutions. It would be helpful if CMS could be clear in the Final Rule whether the Agency’s expectation is that each state seek a State Plan Amendment to be able to take advantage of the relevant VBP provisions being proposed. To do this, the Agency could consider offering a blanket approval rather than requiring individual SPAs or issuing a pre-approved SPA template that States could adopt akin to ‘automatic approval.’ Working with State Medicaid representatives, FoCUS has developed a [toolkit](#) to assist State Medicaid organizations in designing, negotiating and establishing milestone-based contracts that may be helpful to States.

Advance efforts to track outcomes for performance-guarantees. FoCUS experience suggests that States will require resources to track and extract data to evaluate performance in outcomes-based contracts. CMS may be able to help advance real-world data systems capable of national longitudinal patient monitoring, e.g., allowing IT investments needed for performance tracking as part of capability grants; facilitating cross-disease area and cross-sectoral collaborations to create scale in data collection, enabling cross-state/cross-payer interoperability and linking given patient movement across payers.

Consider educational awareness raising among potential future provider centers to ensure appropriate planning for staffing and financial implications of gene and cell therapies – especially those likely to use current transplant and infusion center capacity.

4. We encourage CMS to continue to enable solutions to address patient financing challenges of durable, curative therapies such as co-pays, deductibles, co-insurance and out-of-pocket expenses.

Elements of solutions that have already been offered by stakeholders for some therapies or considered more broadly in the FoCUS discussions include pharmaceutical assistance programs, patient access support programs (not available for patients covered by government payers), provider discounts and charitable write-offs, benefit design waiving co-pays, deductibles and coinsurance for these products, provided it could be done without inducing adverse selection and without discouraging continued innovation in financial service offerings.

5. Additional clarifications/innovation to support VBP arrangements under the Proposed Rule would be helpful

Definition – Value-based Purchasing Arrangement

Additional clarification on CMS' solutions as elaborated in the Proposed Rule would be helpful, including:

- As CMS has noted, *the definition of "substantially"* needs clarification in "substantially link the cost of a drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses."¹ Also, later, CMS provides one example: "(for example, a drug product cost with less than 90 percent of the discounts/rebates tied to the drug's performance not be considered a VBP arrangement)."² For example, does CMS intend to refer to:
 - The magnitude of the discount (e.g., a number greater than the minimum standard Medicaid Rebate as codified in statute)?
 - The share of the discount that is value-based (e.g., X% value-based discount; remainder volume-based or tier placement discount) for a particular payer?
 - The share of the discounts that are value-based versus not value-based in total? *In this case, given the other operational challenges associated with establishing value-based agreements, we believe movement towards value-based purchasing should not be penalized because certain stakeholders choose not to adopt and so we would discourage use of such a definition.*
- *The definitions of evidence-based and outcomes-based measures.*
 - Our group reads this section as **either** evidence-based **or** outcomes-based measures being required to define a VBP arrangement. There will be circumstances under which the accurate collection of outcomes-based measures is infeasible. *It would be helpful to clarify in the Final Rule that only one type of recognized measure must be used in order to define a VBP arrangement.*
 - Currently the proposed definition of outcomes-based measures links to a medicine's actual clinical performance or a reduction in medical expenses. This may not encompass the full potential value to the patient or patient-reported outcomes. As CMS has noted, outcomes-based measures can also include "observing and recording 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 non-medical spending."³ While we are focusing on on-label use, and MDRP establishes the coverage 'floor' of a therapy as the FDA-approved indication(s), there could be situations where allowing VBP agreements on measures not included in the clinical trial would be helpful. For example, situations where an FDA-approved indication is broader than the focus of clinical trials or where payers and

¹ Proposed Rule p. 24.

² Proposed Rule p. 24.

³ Proposed Rule p. 24.

developers want to negotiate individually to a broader set of performance measures than clinical trial endpoints might allow and that patients might prefer. It would be quite limiting on a VBP, and not allow evolution over time as real-world evidence is generate, if parties needed to stick to the strictest evidence generated from 1 or 2 single trials. *Based on FoCUS discussions we would encourage allowing payers and manufacturers to negotiate a different outcomes-based or evidence-based measure, including medical and non-medical spending measures. We recognize that this also touches on issues within the FDA’s regulatory purview.*

Bundled Sale

Additional clarification on CMS’ solutions as elaborated in the Proposed Rule would be helpful, including:

- *Whether the bundled sale solution is a calculation alternative offered under the historical MBP reporting approach and under a value-based payment model or only under one approach?*
- *Whether the bundled sale extension to smooth the discount "over all the units sold under the arrangement in the rebate period" intends the "arrangement" to apply across payers? To help reduce the volatility, particularly for many of the rare-disease-focused gene therapies expected to comprise many of the nearer term durable therapy launches the calculation would need to cross payers. Allowing the option of bundling across arrangements with the same structure across payers at the national level in general or for diseases with a small number of patients to smooth the volatility could offer benefits.*
- *Whether the developer must choose either a bundled or multiple best price approach for a particular therapy or whether the developer may negotiate both, depending on the preferences of their negotiating partners and the product characteristics? For example, for a small population therapy a bundled approach may still not address volatility challenges due to small numbers.*

Definitions – Best Price and Reporting of Multiple Best Prices, Adjustments to Best Price

To enable implementation of VBPs and address the above-mentioned challenges with the current interpretation of Medicaid Best Price, CMS is proposing for a single drug to be made available at multiple price points, each of which would constitute and establish a specific “best price” based on the relevant or applicable VBP and patient evidence-based or outcome-based measures.⁴

As an initial matter, we ask CMS to clarify in the Final Rule that the set of prices or “suite of best prices” should consist of the following elements: (i) the percentage of rebates and price concessions the manufacturer is willing to provide payers for a predetermined outcome; (ii) the patient-evidence based or outcomes-base measure and (iii) the specific timepoint for each outcome. We recognize that best price is a price figure, but believe a price in the context of precision financing solutions is inherently linked to an outcome measure and a timeframe.

By way of example, if a manufacturer contracts with a commercial payer to share 80% of the risk of a therapy based on a patient outcome measured each year for 5 years following administration of the therapy, the established set of prices tied to observed patient outcomes could be represented as follows:

Clinical Metric & Timepoints for Each Metric	Rebate Percentage
Patient Fails to Meet X Outcome @ End of Year 1	80%
Patient Fails to Meet X Outcome @ End of Year 2	60%
Patient Fails to Meet X Outcome @ End of Year 3	40%
Patient Fails to Meet X Outcome @ End of Year 4	20%
Patient Fails to Meet X Outcome @ End of Year 5	5%

⁴ Proposed Rule p. 29.

The proposed rule seems to suggest that if State Medicaid Agencies would decide to track the same outcomes, they could take advantage of the same VBP arrangement offered to commercial payers and consequently take advantage of the offered rebate percentage and of each “best price” based on how well their particular Medicaid beneficiary will be doing.

Clinical Metric & Timepoints for Each Metric	Commercial Rebate Percentage	Best Price for a drug priced at \$100 per patient	Basic Unit Rebate
Patient Fails to Meet X Outcome @ End of Year 1	80%	\$20	\$80
Patient Fails to Meet X Outcome @ End of Year 2	60%	\$40	\$60
Patient Fails to Meet X Outcome @ End of Year 3	40%	\$60	\$40
Patient Fails to Meet X Outcome @ End of Year 4	20%	\$80	\$23.10
Patient Fails to Meet X Outcome @ End of Year 5	5%	\$95	\$23.10

CMS suggests that if a State does not want to track outcomes, their ‘best price’ will automatically revert to the traditional method as calculated based on the price of the therapy when it is sold outside of a VBP arrangement.⁵ *We agree with CMS on the need to maintain the voluntary nature of the current framework for both manufacturers and Medicaid plans and welcome the increased flexibility to allow parties to craft and contract for VBP arrangements based on therapy- and patient population-specific circumstances. However, CMS will need to clarify that State Medicaid Agencies not wanting to track outcomes associated with a multiple best price approach or through unique supplemental rebate arrangements would only be able to obtain a drug rebate based on the traditional formula for calculating the unit rebate amount under existing MDRP regulations. It would be helpful if CMS could also clarify how traditional rebates should be calculated in the event all commercial contracts are VBP.*

To facilitate use of VBP arrangements, we would encourage CMS to identify the simplest way to both calculate and report the available multiple price points or “suites of best prices” to limit complexity for States and developers. Specifically, CMS should identify guidelines for addressing a situation in which more than one VBP arrangement, using a “suite” of best prices approach, is available in the marketplace, how multiple URAs will exist for a single NCD, which could include a VBP arrangement and a non-VBP arrangement, and, working with HRSA, implications for 340B ceiling pricing in a situation with multiple URAs (please see 340B comment below). In general, providing complete illustrative examples of the future options and calculations could be very helpful.

Additionally, it would be helpful if CMS could *clarify in the Final Rule how States will gain access to information on the available multiple price points in a timely manner* given that the price points would be manually reported to avoid any risks of off-cycle payment by manufacturers. This could include the process by which commercial VBP terms are updated and States would migrate to the new terms.

Further areas of useful clarification include:

- *The definition of ‘available at multiple price points’⁶: It is not clear, for example, whether offered by developer, but never agreed to by a commercial payer; having been agreed to in a signed contract even if no volume was reported within a given period; having a reportable transaction in the period; or something else? We suggest that CMS clarify that available means “offered” if there are no transactions in a quarter at*

⁵ Proposed Rule p. 30.

⁶ Proposed Rule p. 29.

the rebate level, or in the event there are transactions, then the payment the manufacturer actually received. This can help ensure that pricing can be relied upon by all parties over a predictable period of time and does not lead to inefficient quarterly fluctuations.

- *What it means for a Medicaid plan to “participate” in the VBP model.* We encourage CMS to require a Medicaid Plan to have a signed VBP agreement in place prior to the quarter beginning to avoid developer fears of *post facto* adverse selection. If CMS agrees, then we request clarification regarding:
 - How must developers present VBP options to States (e.g., lead time prior to quarter) and how will confidentiality be maintained?
 - What information must be shared? As above, we propose the information consist of the following elements: (i) the percentage of rebates and price concessions the manufacturer is willing to provide payers for a predetermined outcome; (ii) the patient-evidence based or outcomes-base measure and (iii) the specific timepoint for each outcome
 - Whether States can have split populations (some beneficiaries under VBP and others not)?
- *Comparability of VBP designs.* We believe – given the diversity of payers and other third parties – that a developer might need to negotiate multiple value-based payment designs with overlapping performance ranges, or simply different measures. We assume that CMS intends for the Best Price for a Medicaid patient to be calculated relative to the price under the same value-based payment design and would encourage CMS to clarify this in the Final Rule. Absent clarity, developers may only be comfortable offering standard national alternatives that might not be of interest to certain individual payers and that could reduce competition.
- *Clarify the reporting unit.* Some companies have turned to third parties for solutions, e.g., payment over time solutions. It would be helpful if CMS could confirm the reportable transaction level for such arrangements (i.e. developer to PBM, not developer to independent PPBM clients, etc.) In addition, it would be helpful to further understand how, for example, TPA business would be reported. Would each self-insured small business ultimately be a reportable unit? This potential fragmentation would result in significant administrative burden and would likely discourage the use of VBP in such cases.
- *Clarify issues related to the warranty model.* Specifically, can CMS confirm the assumption that warranty reimbursements to payers are not reportable transactions, and that warranty premiums paid by manufacturers to the warranty fund are reportable?
- *Implications of solutions for 340B prices.* As the 340B ceiling price is calculated by reference to the Medicaid Unit Rebate Amount and therefore impacted by Medicaid Best Price, *we believe it is critical to clarify – in conjunction with HRSA -- which “best price” or combination of “best prices” is intended to determine the 340B price, as 340B entities could be significant administering providers for many of the gene and cell therapies becoming available.* Without a clear understanding of how, if at all, CMS’s proposal would affect 340B ceiling prices, it seems unlikely a developer would risk reporting multiple best prices. One option could be that the same VBP participation standards apply to 340B entities as to payers and that there might be the same separation of best prices at the 340B level, based on whether the 340B entity enters into a VBP arrangement. Alternatively, an operationally simpler option could be to have 340B reference the non-VBP best prices reported by developers.

12-quarter AMP reconciliation

We applaud CMS’ amplification⁷ of the historical guidance on MBP 3-year (12-quarter) price reconciliation for value-based contracts with a term greater than three years, which addresses a current challenge for multi-year milestone-based contracts and performance-based annuities with terms greater than three years. Limiting an outcome measurement to *only* less than the historical 12-quarter maximum, regardless of the clinical data associated with a given treatment, might jeopardize the usefulness of a value-base contract.

⁷ Proposed Rule p. 59.

Additionally, *CMS could consider confirming, consistent with the current system, that out-year payments in VBP approaches do not need to adjust for the time value of money.*

ASP

The average net sales price received by a developer from all purchasers (ASP) is used by some payers to reimburse providers for medicines purchased and administered by the provider (buy and bill). As currently written ASP takes into account performance rebates that are paid to payers. If a provider purchases a medicine up front and then is reimbursed at a later date as a function of ASP, there can be a difference in reimbursement. The small patient numbers of many of these treatments will also increase the volatility of ASP and magnify the risk of payment volatility to providers. *CMS may wish to consider this interaction and to explore mechanisms to limit this risk in order to support adoption of VBP arrangements.*

* * *

Thank you for the opportunity to submit comments in response to the proposed rule. If you have any questions about this submission please do not hesitate to contact Katie Torrence, Program Coordinator, FoCUS Project, MIT Center for Biomedical Innovation/NEWDIGS at ktorrenc@mit.edu.

Sincerely,



Gigi Hirsch, MD

Executive Director, Center for Biomedical Innovation

Massachusetts Institute of Technology

On behalf of NEWDIGS initiative/Financing and Reimbursement of Cures in the US (FoCUS) Project