

NEW DIGS

FoCUS

Financing and Reimbursement
of Cures in the US

WHITE PAPER



Tools for Implementation of Precision Financing Solutions Within Medicaid Plans

November 20, 2019

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EXECUTIVE SUMMARY

Medicaid is a unique payer in the US healthcare system due to the financial and policy constraints of the program. Since 2017, a specialist FoCUS team has been actively pressure testing precision financing solutions for the program, initially by clarifying the multiple constraints and issues related to implementing alternative financing models in Medicaid. Of the solutions considered, a 1-year milestone-based contract (MBC) was identified as potentially permissible under current Medicaid rules via a state plan amendment (SPA).

In 2018, Oklahoma gained approval from the Centers for Medicare & Medicaid Services (CMS) for a SPA allowing them to engage in MBCs with manufacturers, whereby a supplemental rebate will be paid by a manufacturer if clinical outcomes are not achieved. Colorado, Michigan, and Massachusetts have since obtained similar authorizations.

In this white paper, an overview of MBCs is provided within the context of both Medicaid and the FoCUS project. In addition, the practical process of obtaining a SPA is explained, including how to initiate a SPA application and factors for Medicaid teams to consider before doing so. The potential benefits of MBCs for all stakeholders, as allowed under SPAs, are discussed. Examples of successful SPA applications and a worksheet to assist in subsequent MBC negotiations are provided in the Appendices.

FoCUS continues to research the possibility of implementing multi-year performance-based contracts in the Medicaid program. To enter into such an agreement, Medicaid plans may require a SPA, or to the extent such an arrangement would require exemptions from the requirements of the Medicaid statute, a Section 1115 waiver from CMS. A Section 1115 waiver provides states with a means to test new approaches in Medicaid that differ from what is required by federal law. This approach is more complex than implementing MBCs via SPAs and must be agreed to by the Secretary of the Department of Health and Human Services (HHS). Work continues in this area.

BACKGROUND

FoCUS was launched in 2016 with the aim of developing precision financing solutions to help address the potential significant cost burden created by durable/potentially curative cell- and gene-based therapies entering the US healthcare market. While these innovative therapies have the potential to deliver substantial health benefits for patients that accrue over a long period of time (or even a lifetime), they are associated with high upfront costs and carry an associated risk for payers, as long-term outcomes have often not been established upon the drug's approval. The FoCUS project does not address how to value these therapies or set their prices but seeks to provide financing solutions that will ensure as broad as possible access to patients who would benefit, while balancing sustainability for all stakeholders. FoCUS is multi-stakeholder in nature, with payers, providers, patient advocates, regulators, pharmaceutical developers and financiers working collaboratively to ensure an appropriate balance between industry and public needs.

Since its inception, the FoCUS project has identified multiple financing options to meet the needs of various payer segments and address the therapy characteristics of individual treatments. The four key precision financing solutions identified by FoCUS are:

1. A short-term milestone-based contract (MBC): rebates are linked to performance over less than 2 years
2. A multi-year performance-based annuity (PBA): payments are spread over multiple years, linking each payment to performance
3. Risk pooling
4. Orphan reinsurer and benefit manager (ORB): combines the risk-bearing of reinsurers with the therapy contracting capabilities of pharmacy benefit managers, the provider network-building and medical management capabilities of insurers, and possibly a specialty pharmacy distribution capability.

Medicaid was identified as a unique payer in the US healthcare system early in the FoCUS project, requiring financing solutions that consider the financial and policy constraints of the program as mandated by state and federal regulations.¹ A specialist FoCUS Medicaid team was formed to investigate further whether Medicaid plans can support precision financing solutions in a manner acceptable to all stakeholders. The team identified multiple constraints and issues related to implementing these alternative models within Medicaid, including:

- State-by-state variability in the administration of prescription drug plans: State plans have agreements

with the federal government, which are managed by the Centers for Medicare & Medicaid Services (CMS). These define formulary development and drug contracting. In addition, states have contracts with managed care organizations (MCOs) to administer drug benefits. These may delegate full, partial, or no control over drug contracting.

- Federal pricing regulations: Prescription drugs are subject to the Medicaid Drug Rebate Program (also known as 'best price' rules) and the 340B Drug Discount Program, among other regulations. Average manufacturer price (AMP) is also a consideration, as it is used as the basis for rebates and discounts in both programs.
- Accounting rules on balanced budgets: State governments do not generally make commitments outside of their 1–2-year budget cycle, complicating, if not prohibiting the use of multi-year contracts. Financial recognition rules for states (cash) also differ from plans (accrual).
- Fluctuating population: The Medicaid population can rapidly fluctuate, thereby making tracking of therapeutic outcomes and plan realization of therapeutic benefit challenging for any given treatment.

Even with these challenges, FoCUS members agreed that alternative financing models would benefit Medicaid programs by potentially facilitating sustainable access to durable/potentially curative therapies. As such, the Medicaid project team sought to identify the means by which Medicaid could implement performance-based contracting under current healthcare policy. Two solutions of interest were considered: the 1-year MBC and multi-year PBA.

This paper aims to provide an overview of solutions to implementation challenges for alternative financing and present tools to aid Medicaid plans, pharmaceutical developers and other stakeholders in negotiating contracts based on precision financing solutions.

OVERVIEW OF VALUE-BASED PURCHASING IN MEDICAID

Public and private payers are increasingly moving from volume-based to value-based payment policies, with a focus on alternative financing models. Value-based policies tie payment to positive clinical outcomes and can extend into drug purchasing and reimbursement. For public payers such as Medicaid, one specific model has emerged with applicability to high-cost durable/curative cell and gene therapies: a value-based agreement in which the manufacturer agrees to pay a supplemental rebate if the drug fails to meet pre-specified clinical outcomes.

In 2018, Oklahoma’s Medicaid program led the way for value-based purchasing agreements for pharmaceuticals. Oklahoma gained approval from CMS for a state plan amendment (SPA) allowing Oklahoma to engage in contracts with manufacturers whereby the manufacturer will pay an additional supplemental rebate if clinical outcomes are not achieved. Other states, including Colorado, Michigan, and Massachusetts have obtained similar authorizations.

Massachusetts and New York may provide a pathway for value-based contracting through a new policy of unbundling certain inpatient treatments. In Medicaid’s bundled payment system for medical services, hospitals receive just one payment for all services provided, including the cost of pharmaceuticals. This bundled payment can be a barrier to value-based contracting, making it difficult to tie payment for a drug to value in the hospital setting. However, Massachusetts and New York have begun paying for certain inpatient therapies separately from the bundle, thereby potentially facilitating value-based payment arrangement for these products. No other path currently exists for states to engage manufacturers directly in value-based contracts for pharmaceuticals delivered in the inpatient setting.

INTRODUCTION TO MBCS

How does FoCUS define an MBC?

As a precision financing solution, FoCUS defines an MBC as a contract between a pharmaceutical developer and a payer in which rebates are paid from the developer to the payer based on the agreed performance goal for a treatment within 1 year.

In practice, this means that the full agreed product price is paid following a patient’s treatment (i.e., as usual), but in the case of underperformance, a developer will refund the payer a predetermined amount in the form of a rebate (Figure 1), generally expressed as a percentage of the product’s cost. Performance-based outcome metric(s) are agreed as part of the MBC prior to patient treatment, as well as the mechanics for measuring and adjudicating that outcome metric(s) in the event of a patient not achieving established outcomes within

Massachusetts unbundles inpatient reimbursement for CAR-T

MassHealth has obtained authority from CMS to reimburse hospitals for certain therapies administered in the hospital setting separate from the bundled payment. Specifically, the state would recognize two separate payments to the hospital, one for the therapy (in an amount equal to the lowest of the hospital’s actual acquisition cost, wholesale acquisition cost [WAC], or Medicare Part B rate) and the other for the hospital-related costs. As a condition of making this separate payment for certain therapies, the state may mandate that the hospital make every effort to enter into a value-based agreement with the manufacturers that offer these contracts. Any savings generated by such an agreement are to be passed on to the state. Additionally, the state could collect federal rebates on these drugs, potentially rendering them eligible for value-based agreements with manufacturers. Currently, MassHealth has designated two chimeric antigen receptor T-cell therapies (CAR-Ts) for separate payment as part of its Acute Hospital Carve-Out Drugs List.

the first year following treatment. Failure to achieve the agreed upon outcome at specific time points triggers a rebate from the developer to the payer. If agreed outcomes are achieved, no rebate is given.

The terms of agreement for an MBC will typically be specified as 1 year from the signature date. However, the terms of the agreed performance metric will be defined as 1 year from the date of therapy administration. This creates the need to recognize performance coverage beyond the year of the executed MBC, as performance terms will continue for 12 months from the date of the last treatment administered within the contract year. Terms of the MBC agreement should therefore include one of the following:

1. the initial contract covers the full period until the last outcome assessment

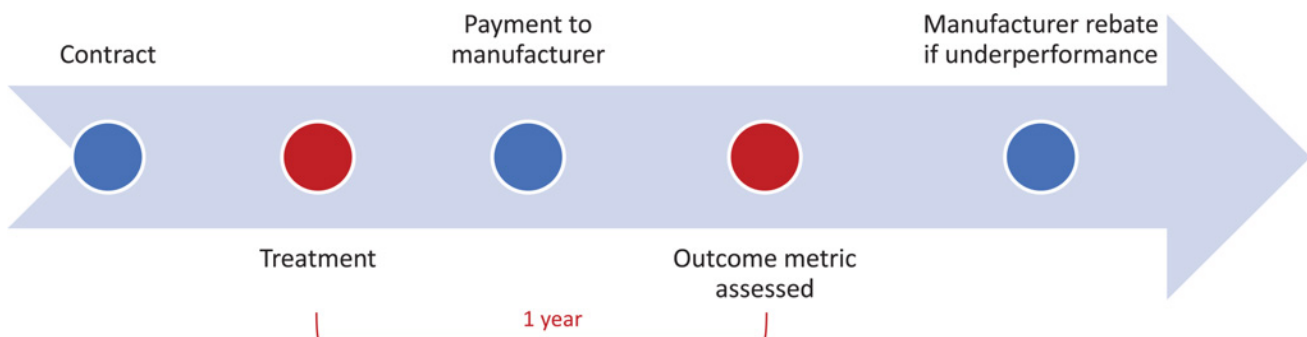


Figure 1. Overview of an MBC timeline

2. a formal extension of the initial contract is required, with termination aligning with the latest date of outcome metric assessment
3. an ongoing contract extension for a second or third year, which will address the timing misalignment.

Terms should also be specified for any rebate payments triggered, clarifying if these would be owed at the time of an outcome assessment, which could be quarterly to yearly, at the end of each year, or at the end of the MBC term.

Addressing financial uncertainty of durable/potentially curative therapies with MBCs

As a financing solution, the 1-year MBC model addresses the short-term performance risk uncertainty associated with a durable/potentially curative therapy. An MBC is the simplest performance-based approach to implement and provides risk sharing for new therapies such as CAR-Ts, which have significant immediate risks associated with their manufacturing and 30-days following cellular infusion, as well as substantial morbidity risk within 1 year. Patient mobility in and out of plans is also less of an issue for measurement tracking with an MBC, as opposed to a longer-term PBA.

An MBC, however, does not materially address the timing mismatch between multi-year benefit accrual and upfront payment. Neither does it address therapeutic durability risk past the first year, the actuarial risks of patient backlog surge nor rare event cost smoothing.

Medicaid value-based purchasing arrangements and MBCs

Value-based purchasing arrangements or value-based contracts (VBCs) are agreements between a drug manufacturer and a payer to link payment for a drug to the value or outcomes it generates. An MBC is a form of VBC where the drug is paid for upfront and rebates are paid to the payer based on failure to meet a predetermined performance or outcome metric(s). The Centers for Medicare & Medicaid Services (CMS) tends to use ‘value-based purchasing agreements’ in their communications, and throughout this white paper, MBC and VBC may be used interchangeably.

It is worth noting that state Medicaid programs cannot pay drug developers/manufacturers directly. Thus providers (hospital, physician, pharmacy) purchase the product that has been specified in a VBC, and the state pays the provider. However supplemental (and federal) rebates are paid directly from the developer/manufacturer to the state Medicaid program.

MEDICAID STATE PLAN AMENDMENT (SPA) FOR MBCS

Understanding SPAs

A Medicaid state plan is an agreement between a state and the Federal government describing how that state administers its Medicaid program.² The agreement ensures that a state will abide by Federal rules for its program activities and includes details of individual coverage, services provided, reimbursement procedures for providers, and administrative activities that are ongoing in the state.

When a state is planning to make a change to its program policies or operational approach, the state sends a SPA submission to CMS for review and approval.² States also submit SPAs to request permissible program changes, make corrections, or update their Medicaid state plan with new information.²

A SPA is required to enable a state Medicaid program to enter into an MBC with a developer. The SPA for VBCs should incorporate language that authorizes the state to negotiate supplemental rebate agreements for pharmaceuticals with drug manufacturers. This type of SPA informs CMS of how VBCs will be incorporated into a state Medicaid plan in general terms; it is not product specific.

Several state Medicaid plans (e.g., Oklahoma, Colorado, Michigan, Massachusetts and Washington) have successfully applied for and received a SPA authorizing the state to negotiate value-based purchasing arrangements with drug manufacturers.³ These state Medicaid plans are thus able to negotiate with developers directly and do not need CMS approval for specific contracts. Contracts are voluntary and conform to current plan operating procedures regarding duration budget planning. Notably best price rules and average manufacturer price (AMP) are not affected by these agreements.

A Medicaid VBC must be structured as a supplemental rebate agreement per CMS. A drug developer must participate in the Medicaid Drug Rebate Program (MDRP) in order to create a VBC with a state Medicaid program because supplemental rebate agreements are contingent upon the federally mandated rebate. Hence, drugs that are not eligible for the federal rebate are not eligible for a Medicaid VBC, which includes drugs purchased through the 340B program. Rebates paid under a CMS-approved supplemental rebate agreement for value-based purchasing are excluded from Medicaid best price (MBP) and AMP. This holds appeal for developers since it them to offer value-based rebates and discounts without impacting MBP and AMP.

A SPA does not expire. As such, a VBC as permitted by a SPA will be subject to the terms of the agreement between a state Medicaid plan and the drug manufacturer and can be

negotiated on a year-by-year basis without CMS involvement. A SPA submission for VBCs can have a proposed effective date from the beginning of the quarter in which it is submitted to CMS, even if approval is received 90 days after the submission. This means that the SPA will be effective from up to 6 months before approval from CMS. In practical terms, this allows VBCs to be negotiated and effective in the same calendar year as the SPA is approved, as long as the VBC agreement date coincides with the SPA date.

Benefits of a SPA authorizing MBCs

The intent of a 1-year MBC for durable/potentially curative high-cost therapy is to provide further rebates than those federally mandated for Medicaid prescription drugs, if the therapy does not provide outcomes that are beneficial to patients and the wider healthcare system. Medicaid State plans benefit from this type of MBC by addressing the short-term performance risk uncertainty associated with a durable/potentially curative therapy. Moreover, since states and manufacturers are not subject to best-price requirements when a Medicaid supplemental rebate is negotiated as part of an MBC, developers may be more willing to engage in putting a meaningful amount of fees at risk. Further, the complexity of calculating best price for patient-level performance is not an issue under this scenario.

Initiating the SPA process

CMS provides information on the SPA review and approval processes and tools for state use in the development of SPA submissions. Further details are available on the [Medicaid.gov website](https://www.medicare.gov/medicaid-rebate). However, these tools do not necessarily provide detailed information around adding a SPA that allows for VBCs.

Examples of successful SPA applications for Oklahoma and Massachusetts that allow each state to enter VBC negotiations with manufacturers are provided in [Appendix 1](#), together with an example of a model value-based supplemental rebate agreement in [Appendix 2](#). As Medicaid state plans can differ significantly, advice should be sought as to the applicability of these examples to an individual state's SPA application.

State Medicaid plans and manufacturers should consider the timeline for a SPA approval before entering negotiations. According to CMS, a state should receive an initial response to a SPA submission within 15 days of receipt.⁴ In 2016, the median number of days between SPA submission and approval was 82. The Oklahoma SPA for VBCs was initially received by CMS on March 29, 2018 and approved on June 27, 2018 – 91 days following submission. The approval for Massachusetts' SPA took slightly longer: it was received by CMS on March 12, 2019 and approved on July 31. Interestingly, the approval was deemed effective from January 1, 2019.

Additional factors for consideration

There are several additional factors that state Medicaid plans should consider in terms of their ability to negotiate an MBC before submitting a SPA. For example, plans should ensure their state procurement rules allow negotiation of an MBC/VBC for a specific treatment with developers. States using purchasing collaboratives will need to evaluate these contracts for alignment with the goals of a value-based purchasing agreement. Many of these one-time high-cost treatments would traditionally be administered under the medical benefit. Plans may need to carve reimbursement out of the bundled payment to give visibility to the treatment and eligibility for an MBC.

EXECUTION OF MBCs IN MEDICAID

An MBC is generally negotiated between a state Medicaid plan and drug manufacturer, although additional parties may be involved, such as a purchasing collaborative. Key elements of an MBC are common to all contract negotiations. Preparation by manufacturers and systematic obtainment of these data points can facilitate conversations and reduce administrative burden for both parties. These elements include manufacturer contact details, product details, population/therapy specific details, proposed performance-based measures and financial metrics. A worksheet to assist in negotiating an MBC is available in [Appendix 3](#) and can be modified to meet individual needs.

Specific product discussions between state Medicaid programs and manufacturers should be entered into with clear priorities, such as specific financial targets for performance, timelines, and an understanding of the additional internal burden incurred by these milestone-based agreements.

In addition to providing the resources and funding to write a SPA submission, both the state and the drug manufacturer will require resources to negotiate, measure, and administer MBCs. This burden can be significant and should be carefully considered as part of the financial implications of each contract negotiation. Examples of administrative functions on the Medicaid side include data pulls, meetings, clinician time, and ancillary staff time. Manufacturers will also require resources to support these contracts. It may not be feasible for manufacturers and state plans to engage in MBCs for treatments of very rare diseases where a low number of patients are expected to be treated.

HOW ARE MANAGED MEDICAID PLANS AFFECTED?

Managed Medicaid plans play an important role in delivering Medicaid benefits. Each state Medicaid agency decides whether they will use Medicaid Managed Care Organizations (MCOs) to manage some or all the Medicaid benefit. Part of

this decision is how much of the pharmacy benefit should be included in the contract. Examples of functions that can be outsourced include formulary/preferred drug lists; rebate contracting/management; and prior authorization services. Drugs contracted by the MCO are subject to best price calculation.

To allow for more direct control and oversight of the pharmacy spend, the state agency may carve some drugs, particularly high-cost drugs, out of the MCO contract. Or, the state may decide to include pharmacy in the MCO contract, but designate classes for which the state wants to negotiate rebates and establish the formulary. These options result in a complex matrix of MCO contracts that vary across states and are nuanced within states. As such, the applicability of MBCs for Medicaid MCOs is low.

LIMITATIONS OF THE SPA: PATHWAY FOR IMPLEMENTATION OF MULTI-YEAR PERFORMANCE-BASED AGREEMENTS

Understanding the potential need for 1115 waivers

When Congress adopted federal laws governing Medicaid drug reimbursement, it did not contemplate value-based contracting arrangements or the complexities of high-cost one-time treatments.

Under a 1-year MBC, states and manufacturers are not subject to Medicaid best price rules, as the discount is provided through a Medicaid supplemental rebate. However, some VBP arrangements—such as a longer-term PBA – do not clearly fit within the traditional supplemental rebate mechanism and therefore may fall outside the MBP exception.⁵ In addition, state plans currently cannot pay manufacturers directly. Moreover, it is not clear that current state plan authority allows for administration of multi-year PBAs based on the duration of the evaluation period.

A PBA begins with a contact between the manufacturer and the payer in which an agreement is reached to spread

payments across multiple years (*Figure 2*). The initial payment follows treatment and additional payments are linked to the performance of the treatment over time.

To engage in a PBA, a state Medicaid plan may need to seek a waiver from CMS, depending on the terms of the contract. A Section 1115 waiver essentially provides states with a means to test new approaches in Medicaid that differ from what is required by federal regulations – that is, specific provisions of major health and welfare programs, including certain requirements of Medicaid, are waived.⁶ Waivers generally reflect priorities identified by states and CMS. States can obtain broad and comprehensive waivers that make changes to Medicaid eligibility, benefits, and provider payments, if the Secretary of the Department of Health and Human Services (HHS) agrees that the initiative is likely to assist in promoting the objectives of Medicaid. Waivers are typically approved for a 5-year period and can be extended, typically for 3 years.

The FoCUS Medicaid project team is continuing to research the barriers to PBAs and the potential use of 1115 waivers and other means of implementing PBAs within state Medicaid plans. Developments regarding the pathway to PBAs will be communicated as available.

CONCLUSIONS

This white paper has focused on the practical aspects to aid implementation of MBCs between state Medicaid programs and developers. FoCUS continues to work with state plans, CMS, and other stakeholders to address the obstacles that challenge longer-term PBAs and other alternative contracting solutions.

Implementation of precision financing solutions is a challenge for state Medicaid payers given the complexity of the environment. FoCUS has aimed to provide example templates within this white paper to support state Medicaid plans, manufacturers, and other interested parties in

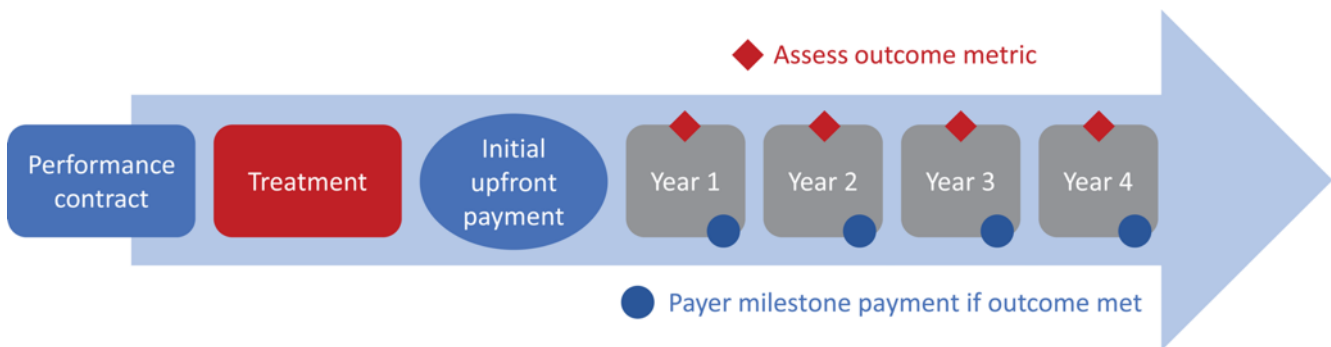


Figure 2. Overview of a PBA timeline

furthering dialogue around MBC and value-based arrangements. These may not be applicable to specific state plans. External council may be needed to define specific contracting arrangements.

ABOUT FOCUS

The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable and potentially curable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by these therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement in this endeavor.

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APPENDIX 1: EXAMPLE OF APPROVED SPA APPLICATIONS

The pdf links below contain the approval letters and CMS 179 forms from the Oklahoma and Massachusetts SPA applications to CMS for value-based supplemental rebate agreements with drug manufacturers. All approved SPAs are publicly available from CMS at:

<https://www.medicaid.gov/state-resource-center/medicaid-state-plan-amendments/index.html>.

Click on the links to access the documents.

[Massachusetts – Approved SPA](#)

[Oklahoma – Approved SPA](#)

APPENDIX 2: EXAMPLE OF A MODEL VALUE-BASED SUPPLEMENTAL REBATE AGREEMENT

The pdf link below is to an example of a model Value-Based Supplemental Rebate Agreement. This type of model agreement would potentially accompany a state SPA application. For example, in the CMS approval letter for the Oklahoma SPA application (see pdf link above), CMS clarifies that “These contracts will be executed on the model agreement entitled ‘Value-Based Supplemental Rebate Agreement’ submitted to CMS on March 29, 2018 and authorized for use beginning January 1, 2018.”

The FoCUS group has provided this example model agreement with the caveat that users should not construe this example as advice for state Medicaid decision-makers. Teams should seek independent advice regarding their own state’s SPA applications.

[Model Value-Based Supplemental Rebate Agreement](#)

APPENDIX 3: WORKSHEET FOR NEGOTIATING AN MBC

FoCUS has developed a worksheet to assist in negotiating an MBC. The form and instructions begin on the following page and are also provided as editable pdf below. Users are welcome to copy and modify the worksheet to meet individual needs.

[Worksheet for Negotiating an MBC](#)

Worksheet for Negotiating Value-Based Contract

Drug manufacturer contact details			
1. Name:		2. Title:	
3. Phone:		4. Email:	
5. Address:		6. Proposed effective date:	

Contract terms for consideration			
<i>Product details</i>			
7. Name of covered product:		8. Name of manufacturer:	
9. Route of administration:		10. Site of care:	
11. Covered/current product status:		12. Preferred status:	
<i>Details of proposed performance-based measurement(s)</i>			
13. Intervention population:			
14. Outcome-based benchmark:			
15. Evaluation methodology:			
16. Source of data:			
17. Timeframe for outcomes data collection			
18. Preferred status:			
19. Proposed data aggregator for outcome and evaluation of performance:			
20. Proposed audit rights of performance evaluation:			

Financial metrics	
21. Base administration fee(s):	
22. Payment for adherence-based benchmarks:	
23. Outcome-based supplemental unit rebate amount (URA):	
24. Rebate calculation methodology:	
25. Settle-up period:	

Worksheet for Negotiating Value-Based Contract

INSTRUCTIONS

Drug manufacturer contact details

Block 1 – Name –

Block 2 – Title –

Block 3 – Phone –

Block 4 – Email –

Block 5 – Address –

Block 6 – Proposed effective date –

Contract terms for consideration

Block 7 – Name of covered product – Enter the 11 digit NDC

Block 8 – Name of manufacturer –

Block 9 – Route of administration –

Block 10 – Site of care –

Block 11 – Covered/current product status –

Block 12 – Preferred status – Enter the proposed changes, with justification

Block 13 – Intervention population – Enter the the population to be measured

Block 14 – Outcome-based benchmark –

Block 15 – Evaluation methodology – Enter how the outcome is measured

Block 16 – Source of data – Enter the data source; for example, claims, patient-reported claims

Block 17 – Timeframe for outcomes data collection –

Block 18 – Preferred status – Enter proposed changes, with justification

Block 19 – Proposed data aggregator for outcome and evaluation of performance – Describe who is responsible for data collection

Block 20 – Proposed audit rights of performance evaluation –

Financial metrics

Block 21 – Base administration – Enter the amount paid by the manufacturer to cover costs related to VBC

Block 22 – Payment for adherence-based benchmarks – Enter the amount paid by the manufacturer

Block 23 – Outcome-based supplemental unit rebate amount (UBA) – Enter the amount beyond the rebate owed based on VBC metrics

Block 24 – Rebate calculation methodology –

Block 25 – Settle-up period - Enter the settle-up period after close of contract utilization period, typically 90 days