

A New Frontier - Value Based Contracting with Provider or Hospital Systems "The Product Guarantee" An "SME" CASE STUDY



"In the rapidly changing healthcare landscape, payers are asking providers to shift from volume-based care (fee for service) to a value-based reimbursement structure (fee for value) with a population health approach."

Payer-Provider Reimbursement Contracts Are Changing Actual Care Decisions. In the paradigm shift away from "Fee for Service" to "Value Based Reimbursement", products marketed by US Device or Drug Manufacturers longer represent a "revenue" opportunity where the provider bills the payer at cost plus fees, but may now represent a significant and *avoidable* "cost".¹

For example, in situations where a novel product is reimbursed by the payer under a "DRG" (Diagnosis Related Group), flat fee or fixed fee schedule, a hospital or outpatient provider may wish to avoid the use of that product unless it can be demonstrated to shave time off of the admission or create clear savings within the institution during that care episode or hospitalization; they must be able to justify added costs.

This means that the manufacturer must make a compelling case for measurable, superior outcomes realized by the provider and patient alike, under the reality of the provider's predominant local payer mix and reimbursement schemas. Even as they offer traditional pricing discounts through Group Purchasing Organization (GPO) contracts or chargebacks, Manufacturers must put forth new efforts to understand these trip wires that may kill a product's opportunity to be appropriately utilized within the FDA labelling for a given disease.

Value Based Contracting Between Manufacturers & Providers. While a manufacturer must be ever-vigilant and only engage with providers in legitimate ways, steering clear of "anti-kickback" allegations and avoiding complex government pricing challenges, the company must also consider that a large rebate to a Payer often does *nothing* to enable a product's use in a facility or by a physician group where payer-to-provider terms create unsurmountable reimbursement hurdles detrimental to the provider.

Using a fictitious product, CDIFFEX, which reduces recurrences of Clostridia Difficile Infections (CDI), this Case Study illustrates how a manufacturer can address the provider's concern for successful product outcomes weighed against its cost under a fixed-fee reimbursement where the alternative product is only one-tenth of the cost with slightly less favorable outcomes. In this Case Study, the manufacturer continues to offer a GPO contract to the facility but offers a full refund (at GPO price) for any patient that suffers a documented recurrence within a time window. Since our drug is often started there, the hospital is interested in having no readmissions, it is willing to adopt the use of CDIFFEX in a specific patient population. (Many other Provider VBC designs are possible!)

¹ Population Health Management
<http://www.mckesson.com/population-health-management/population-health/know-the-challenges/> Taken 11/28/2017.



Product Guarantee Project Snapshot –

Methodology: Each unique project undergoes the same basic process before it can be proposed to and implemented by any number of project partners who may independently elect to participate. In this instance, a short “Baseline” project is advisable to assure manufacturer and Provider facility staff have appropriately aligned expectations and capacity.

1. **Project Definition Phase.** SME Health Systems resources work directly with the manufacturer and its team of consultants and managers to define the needed flexible data container for this project. At this phase the data fields sought² and the flow of collection are mutually agreed.
2. **VBC “Product Guarantee” Form Design Phase.** VBC Product Guarantee forms are designed for data collection, and modified based on feedback from the sponsor. A key need in this project is to understand WHY a given patient had a recurrence, so information about co-morbidities, other drugs, and compliance, is part of what is gathered.
3. **Form Testing Phase.** The forms are tested for flow and data output for future analysis.
4. **Project Launch Phase.** The forms are ready for the sponsor to send to project partners for consideration.
5. **Partner Engagement, Project Proposal & Acceptance.** After an introductory discussion around mutual interest, the project is proposed by the manufacturer as a Project Sponsor and is voluntarily accepted by the Risk-Taking Provider as a Project Partner. The parties share a standard Master Service Agreement and Project Agreement, using MySME Manager™. Once they accept the project, they can begin to collect data, and submit VBC Product Guarantee invoices, as agreed.
6. **Project Administration.**

- Data is collected as part of the submission for each Product Guarantee invoice submitted. Since the data is presented in a homogenous way, it can be compiled by the manufacturer Sponsor for comparative analysis.

- In this Use Case, the data required includes the count of the number of units of CDIFFEX supplied to the patient by the Provider and an assessment of Compliance. The invoice total is calculated based upon the off-invoice acquisition price, a WAC on the date dispensed times a discount, or a contract price.

7. **Regularly Scheduled Project Meetings.** As the life of the arrangement proceeds, the parties hold touchpoint / Project Meetings on a scheduled basis (monthly or quarterly or as otherwise necessary) at the Partner’s site to track progress and discuss any process challenges identified.

Partner Ccd PPLAWTOMM Welcome! Encrypted Login 60
 Sponsor Ccd PSAMBIENT Project ID 235 Orig C Diff Diagnosis Date 01/01/2017
 Target VBC Product Name CDIFFEX Cdiffex Start Date 01/03/2017
 Patient First Name Hania Patient Date of Birth 05/01/1959 Cdiffex End Date 01/17/2017
 Patient Middle Initial H Patient Ref Code Hs-Hs11760-MR32522 Recurrence Date 02/15/2017
 Patient Last Name Haniou Note: All Shaded Fields Have HIPAA & Will Be Encrypted on Export
 Medical Record # MR32522

Recurrent CDIFF after Full Course Treatment with CDIFFEX, cont.

7. Refund Request Confirmation

Please note the number of doses & NDC of CDIFFEX for which you are seeking refund.

Brand Name	Generic Name	Strength	NDC Code (Hosp or Retail)	Dosage Form
CDIFFEX	Sampsonin	250mg	1234978920	Powder Pack
Refund Basis	WAC per Unit	Contract Price	Units Administered	Refund Amount Requested
Contract Price	\$3.750	\$1.0005	13	\$533.007

Required Follow Up Q & A

1. Was this patient compliant with the proper administration of CDIFFEX for the time period associated with this refund request?
 Yes No
2. Describe why you answered the question on CDIFFEX compliance the way you did in the above question.
 Patient Was In Facility For These Doses, Not Doing Self Care
3. Describe what product(s) was/were used subsequent to CDIFFEX was used to treat this patient.
 Select all applicable, modify as needed in table.

Product Name	Treatment Dose	Treatment Duration in Days	Is Patient Currently On?
Bezlotoxumab (Zinplava) Infusion	700mg	1	No

4. Check those treatments required to treat C Difficile Infection within 90 days of the recurrence for this patient. (Press Ctrl-Shift Buttons to select multiple)

- CDI Related Hospitalization
- CDI Related GI Procedure - Fecal Transplant
- CDI Related GI Procedure - Other
- CDI Related Outpatient Treatments
- CDI Related IV Outpatient Antibiotics
- CDI Related Surgery

5. What is the current status of the C Difficile Infection in this patient? (Select best answer)

1. The data required for this project are extracted from the Provider’s (MIS) Management Information Systems and subsystems, as well as Electronic Medical Records for patients encountering a CDI recurrence, reporting at a patient level, with HIPAA fields encrypted to the manufacturer Sponsor but visible to the Provider.



How Parties Benefit from VBC Project Enablement

SME Health Systems Offers

- A technical framework and help desk (MySME Manager™) to enable documentation, data, and billing processes between manufacturers (Sponsors) and various healthcare providers, payers or hospitals (Partners) for mutually agreed finite projects.
- Flexible data collection containers that hold the requisite VBC, RWE or project data
- An invoice process for each VBC product guarantee project, in accordance with the mutually agreed terms and conditions. The invoice is generated by the Partner and submitted to the Sponsor, along with the agreed data.
- Assistance with solicitation and support of Project Partners (hospitals, payers, providers or specialty pharmacies).
- SME Health Systems receives administrative fees from the Sponsor that support its activities (not tied to the price of the product).

Manufacturer Needs Addressed

- A means to gather data in HIPAA compliant and consistent way across any number of Partners contributing toward homogeneous VBC data.
- A means to develop meaningful local payer & provider relationships to support Safety & Medical Effectiveness or VBC projects and dialogue.
- A means to understand the impact of the product and its cost on the "Total Cost of Care" for the provider and patient.

Payer Needs Addressed

- A legitimate means to engage with manufacturers for assembling and managing VBC data from MIS or other subsystems.
- A means to engage in Value Based Contracting that requires no new technology costs, using data extracted from existing systems and saved to a desktop.
- HIPAA compliant data procedures

For more information, please email Terri Bernacchi at tbernacchi@smehealthsystems.com or Dr. Gil Mettler at gil@healthadvisoryprofessionals.com.

Invoice
 Number: AMB-3232
 Date: 09/26/2017
 Due Date: 10/26/2017
 Purchase Order Number: AMB-33252

Bill To: AmbientBioLabs
 Address: 863 Thorne Drive
 Contact: Shawna Conner
 Phone: 410-222-9541
 Email: shawna.conner.ambient@healthadvisoryprofessionals.com

Supplier: Lawton Internal Medicine Associates
 Address: 1518 Sixtieth Street
 Contact: Marmie Lapham
 Phone: 262-657-6672
 Email: marmie.lapham.ima@healthadvisoryprofessionals.com

Project ID	Description	Nbr of Units	Nbr of Instances	Unit Amount	Amount
236	Project: CDIFFEX Recurrence Guarantee	533.00	1	\$1.00	\$533.00

Invoice Total \$ 533.00

