ANALYSIS OF HYPOTHETICAL ARRANGEMENT #1
UNDER ADVAMED PROPOSED SAFE HARBORS FOR
VALUE-BASED PRICING ARRANGEMENTS AND VALUE-BASED WARRANTIES

At the core of our proposal for a Value-Based Arrangement (either the Value-Based Pricing Arrangement or the Value-Based Warranty) is shared risk between the parties to achieve a predefined, objective outcome.

I. INTRODUCTION

This hypothetical arrangement (the Arrangement) involves a medical device manufacturer (the Manufacturer) selling to its hospital customers (the Hospitals) the following bundle of items and services for a price of $175,000:

- Medical technology (the Device);
- Clinical Consulting Services to address gaps and improve processes; and
- Efficiency Consulting Services and Solutions to improve supply chain efficiencies.

Each component of the bundle is explained in detail below. The $175,000 sale price represents a 30% discount from the total fair market value of the bundle ($250,000), as explained further below.

Part 1: The first purpose of the Arrangement is to allow the Manufacturer to provide the Hospitals with a bundle of items, at a discounted rate, and services designed to increase the Hospitals’ employed physicians’ adenoma detection rates (ADRs) associated with screening colonoscopies performed by such physicians using the Device, with the Manufacturer providing an additional discount if the ADR target is not achieved.

- A physician’s ADR is the rate at which the physician detects at least one adenoma (polyp) in individuals over the age of 50 undergoing a screening colonoscopy, and is a nationally-accepted quality benchmark. It is well-established that the more proficient a physician is at detecting precancerous polyps, the less likely it is that his or her patients will develop colon cancer. Thus, a physician’s ADR is a direct reflection of the quality and effectiveness of his or her colonoscopies, with higher ADRs representing higher quality. Because improving physicians’ ADRs reduces their patients’ risk of developing colon cancer—an outcome that is desired by payors and patients alike—payors incentivize higher physician ADRs through reimbursement programs, such as by offering additional reimbursement to those physicians whose ADR surpasses a certain threshold. Medicare, for example, has incorporated ADR as a quality measure under the new Merit-Based Incentive Payment Program (MIPS), as explained in more detail below. Other payors may have similar physician incentives and/or separate reimbursement incentives for facilities (such as the Hospitals) which take steps to maximize their employed or contracted physicians’ ADRs; for example, through purchases of higher quality medical technology or investment in physician training and education programs.

Part 2: The second purpose of the Arrangement is to allow the Manufacturer to provide Efficiency Consulting Services and Solutions as part of the bundle, which are designed to improve the Hospital’s supply chain efficiencies and decrease the Hospital’s costs. The Efficiency Consulting Services and Solutions are provided under terms with an outcome goal that the Hospitals will save $X. If the Hospitals save money, then the Manufacturer will be compensated 10% of the savings up to $X and 40% of the savings above $X.
For purposes of the Arrangement, the Hospitals employ all of their physicians\(^1\) and compensate them pursuant to terms set forth in written employment agreements. The Hospitals bill payors, including federal health care programs, for all services the employed physicians provide to the Hospitals’ patients under their employment agreements, and collect all reimbursement owed by such payors’ for the physicians’ services. Further, the Hospitals handle, on the physicians’ behalf, all reporting obligations associated with the physicians’ eligibility for such reimbursement, such as the reporting of quality measures under MIPS. Any bonuses paid under MIPS or other incentive-based payment systems for the employed physicians’ performance are paid to the Hospitals.\(^2\)

II. THE ARRANGEMENT

A. THE BUNDLE

1. THE DEVICE

The Device identifies, diagnoses, and removes adenomas in the colon. It consists of a scope, tube, camera, monitor, and more, and the bundle includes disposable instruments for polyp removal. The fair market value of the Device is $150,000.

2. CLINICAL CONSULTING SERVICES

The Manufacturer would also provide consulting services to the Hospitals (Clinical Consulting Services), falling into two categories. First, the Manufacturer would perform Consulting Services prior to the Hospitals’ adoption of the Device (Pre-Adoption Clinical Consulting Services). As part of these services, the Manufacturer would perform an analysis of the Hospitals’ and their employed physicians’ current practices and the physicians’ current ADRs. Specifically, the Manufacturer would collect and analyze data from the Hospitals to determine current ADRs for the physician employees, and to identify gaps or areas where process improvements might be made to optimize outcomes. Based on its assessment of current practices, the Manufacturer would make recommendations on process modifications as appropriate.

Second, the Manufacturer would perform additional Clinical Consulting Services after the Hospitals begin using the Device (Post-Adoption Clinical Consulting Services). Specifically, the Manufacturer would perform an outcomes analysis after the Hospitals’ adoption of the Device, and would review and make recommendations on any further process improvements it might identify.

The fair market value of the Pre-Adoption Clinical Consulting Services is $40,000, and the fair market value of the Post-Adoption Clinical Consulting Services is $20,000.

3. EFFICIENCY CONSULTING SERVICES AND SOLUTIONS

The Manufacturer would also provide efficiency consulting services to the Hospitals (Efficiency Consulting Services). First, the Manufacturer would perform an analysis of the Hospitals’ supply chain operations. Specifically, the Manufacturer would collect and analyze data from the Hospitals to determine areas where supply chain operations could be optimized (while still maintaining an array for physician choice) to yield cost savings. Based on its assessment of current practices, the Manufacturer would make recommendations optimize systems and processes and deploy solutions where appropriate.

The fair market value of the Efficiency Consulting Services and Solutions is $40,000.

4. TOTAL FMV OF THE BUNDLE

Thus, the total fair market value of the bundle is $250,000 ($150,000 + $40,000 + $20,000 + $40,000).

\(^1\) The physicians for purposes of the Arrangement are all gastroenterologists who perform colonoscopies among other services for the Hospital’s patients.

\(^2\) The Arrangement contemplates that all compensation paid by the Hospitals to the physicians, including any pass through of any portion of such bonuses from the Hospital to the physicians, is appropriate under applicable fraud and abuse laws.
B. ARRANGEMENT PART 1: OUTCOME WARRANTY AND RISK/REWARD SHARING FOR ADR OUTCOMES

Under the Arrangement, the Manufacturer effectively warrants to the Hospitals that use of the Device for screening colonoscopies will result in the employed physicians’ achieving a specified increase in ADRs for a specified time period, as compared to ADRs previously achieved, thereby triggering increased physician reimbursement under MIPS and potentially triggering increased physician and facility reimbursement under other payors’ quality incentive programs.  

If this warranted outcome is not achieved, the Manufacturer will provide the Hospitals with a $75,000 rebate, thereby decreasing the Hospitals’ total purchase price from $175,000 to $100,000. This represents a 60% discount from the total fair market value of the bundle ($250,000).

If the warranted outcome is achieved, the Hospitals will share with the Manufacturer a portion of the increased facility and/or physician reimbursement they receive under MIPS (or any other specified reimbursement incentive program that is based on increased ADRs). Specifically, the Hospitals will pay the Manufacturer 30% of the total amount of additional reimbursement they receive as a result of purchasing the bundle and becoming eligible for ADR reimbursement incentives, as compared to what they would have otherwise received had they or their physicians not been eligible for such reimbursement incentives.

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3 Payor Incentives for Increased ADR

While Medicare does not adjust the facility’s reimbursement based on the ADR of the physician performing the service (see Attachment A providing a comprehensive summary of reimbursement for colonoscopy procedures), under the Merit-Based Incentive Payment System (MIPS) for physicians, “Screening Colonoscopy Adenoma Detection Rate” is one of the quality measures for which CMS makes quality incentive payments based upon physicians’ reporting and performance of such rate. CMS both incentivizes physicians to report, and now uses as part of its scoring process under MIPS.

For purposes of MIPS, ADR is defined as “The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.” It is an outcomes measure (rather than a process measure), and it is also considered a high-priority measure. If physicians choose ADR as one of the measures that will be used to calculate their score, CMS will measure ADR against certain benchmarks (shown in the table below), and assign points based on how the physician’s ADR compares to other physicians on a nationwide scale. The following is an excerpt from the detailed description of scoring (note, the ADR quality measure does have a benchmark):

The Quality performance category is worth 60% of the overall MIPS final score. For the transition year, clinicians will automatically receive a minimum of three points for completing and submitting at least one quality measure. If they report fully and submit six measures, or a specialty measure set, they will be scored on all the measures. If they are in a group of more than 15 clinicians, they will also be scored on a population-based measure, known as the All-Cause Hospital Readmissions measure, if they exceed a case volume of more than 200 Medicare patients. CMS will use national benchmarks as the basis for scoring. Each quality measure is converted into a 10-point scoring system. Performance on quality measures is broken down into 10 “deciles,” with each decile having a value of between one and 10 points. The deciles will be based on stratified levels of national performance (benchmarks) within that baseline period. A clinician’s performance on a quality measure will be compared to the performance levels in the national deciles. If a measure can be reliably scored against a benchmark, then clinicians can receive 3-10 points. There is a bonus point for each high priority measure. CMS will also give a bonus point due to the fact that ADR is a “high priority” measure. Finally, in connection with the transition to MIPS, CMS gives bonus points for simply for reporting at least one quality measure including ADR.

The benchmarks for the ADR quality measure are as follows:

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<th>Measure Name</th>
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<th>Submission Method</th>
<th>Outcome Type</th>
<th>Decile 3</th>
<th>Decile 4</th>
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<th>Decile 8</th>
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<td>Screening Colonoscopy Adenoma Detection Rate</td>
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<td>Registry / QCDR</td>
<td>Out-Come</td>
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<td>41.86 - 45.70</td>
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<td>56.52 - 63.40</td>
<td>63.41 - 80.32</td>
<td>80.33 - 100.00</td>
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</tbody>
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C. ARRANGEMENT PART 2: SHARED SAVINGS DUE TO INCREASED EFFICIENCIES

Part 2 of the Arrangement relates to the Efficiency Consulting Services and Solutions component of the bundle. These services and solutions are related to the Device, its servicing, and its consumable components. This aspect of the Arrangement sets an outcome goal of the Hospitals achieving a savings of $X if the recommended processes and solutions are implemented to optimize the supply chain. Under Part 2 of the Arrangement, if the Hospitals save money, then the Manufacturer will be compensated 10% of the savings up to $X and 40% of the savings above $X.

D. STRUCTURE OF THE ARRANGEMENT

1. WRITTEN AGREEMENT

The Manufacturer and the Hospitals would enter into written purchase agreements that set forth these terms prior to the Hospitals’ purchase of the bundle, which include the objective mechanism for determining the amount of the price adjustments in Part 1 and Part 2 of the Arrangement. Among other things, the purchase agreement would require the Hospitals and their employed physicians to report ADRs to CMS for use in CMS’s calculation of such physicians’ final score under MIPS.

The Arrangement as articulated in the purchase agreement would also specify that (a) the patients seen under the Arrangement must meet nationally recognized screening criteria/ guidelines [no additional patients are pulled in] and (b) the Arrangement is dependent upon the Hospitals’ implementation of the recommended clinical and efficiency improvement measures.

2. ITEMIZED DESCRIPTION OF BUNDLE

The purchase agreement would also set forth details regarding the included Clinical Consulting Services and Efficiency Consulting Services and Solutions, including an itemized description of the services, and a schedule showing when the services will be provided.

3. ACCURATE REPORTING

Each Hospital would report its net cost\(^4\) for the bundle in its annual cost report under the appropriate cost centers. The Hospitals would bill payors for colonoscopies performed using the Device in the same manner they would bill any other colonoscopy, subject to payor-specific billing requirements and guidelines. None of the Clinical Consulting Services or Efficiency Consulting Services and Solutions provided by the Manufacturer to the Hospitals would be billed to any federal health care program by either the Hospitals or the Manufacturer.

III. ARRANGEMENT PART 1 ANALYSIS

[ADR Outcome Warranty and Risk/Reward Sharing]

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items and services reimbursable by a Federal health care program. See 1128B(b) of the Social Security Act (the Act). Where remuneration is offered purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000);

\(^4\) Such net cost will vary depending on whether the outcomes warranty rebate is paid in accordance with the terms of the purchase agreement or whether any incentive payments are shared with the Manufacturer.
Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128(B)(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The U.S. Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for participating in arrangements that qualify for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The proposed safe harbor for value-based pricing arrangements would protect certain price adjustments and certain services furnished by a seller to a buyer, provided that certain standards are met. Likewise, the proposed safe harbor for value-based warranties would protect certain outcome assurances furnished by a seller to a buyer provided that certain standards are met.

A. PROPOSED VALUE-BASED PRICING ARRANGEMENTS SAFE HARBOR

The proposed value-based pricing arrangements safe harbor protects “value-based price adjustments” and “value-based services” offered by a “seller” to a “buyer” in connection with a “value-based pricing arrangement” (each term as defined in the proposed safe harbor) provided that (as applicable to this Arrangement):

- The terms and conditions of the price adjustment are fixed and disclosed in writing at or in advance of the time of purchase;
- The value-based services to be provided are identified in writing and disclosed to the buyer at or in advance of the time of purchase;
- The buyer reports to Federal health care programs the price it paid (i.e., its net cost) if and as required by statute, regulation, demonstration or contract (accounting for any price adjustment or allocation of value among components of a bundle);
- The buyer does not submit a claim for any value-based services separate and apart from the buyer’s claim for the reimbursable item and/or services included in the value-based pricing arrangement;
- The seller does not submit a claim for any value-based services;
- The seller assists the buyer in meeting any applicable price reporting obligations to Federal health care programs by providing a reasonable allocation of value among components of the bundle upon the buyer’s request; and
- The seller does not otherwise impede the buyer in meeting any applicable price reporting obligation to Federal health care programs.

As an initial matter, the Arrangement meets the definitional aspects of the proposed safe harbor. First, the Hospitals meet the proposed safe harbor’s definition of “buyer” because they receive reimbursement under Federal health care programs for services they provide to patients. Likewise, the Manufacturer is a “seller” under the proposed safe harbor’s definition because it supplies to buyers (i.e.,
Hospitals) a reimbursable item—i.e., the Device (reimbursement for which is included in the payment rates
set by payors).

Both the Arrangement’s potential $75,000 price reduction and the sharing of any reimbursement incentive
payments due to increased ADRs constitute “value-based price adjustments” under a “value-based pricing
arrangement,” as price adjustments which are “conditioned and/or calculated based upon one or more
clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated
with the value of the seller’s reimbursable items and/or services purchased by the buyer.” Specifically,
the price adjustments relate to the value of the Device, as reflected in the ADRs achieved—a measurable
clinical metric.

The Clinical Consulting Services and Efficiency Consulting Services and Solutions that are provided by
the Manufacturer to the Hospitals meet the proposed safe harbor’s definition of “value-based services”
which includes “analysis, software, equipment, information and/or services provided or made available by
a seller as part of a value-based pricing arrangement, for no charge apart from the buyer’s price or net cost
for the reimbursable items and/or service to which the value-based pricing arrangement relates” for one or
more specified purposes. The value-based services provided in connection with the Arrangement are
offered for three qualifying purposes under the proposed safe harbor as follows:

- First, the Arrangement involves value-based services offered for the purpose of measuring,
collecting, calculating the metric(s) upon which the value-based pricing adjustment is payable.
Specifically, the Consulting Services are intended to calculate the Hospitals’ employed
physicians’ ADRs before and after the Hospital’s adoption of the Device, with a pricing
adjustment of $75,000 payable if a specified ADR increase is not achieved.
- Second, the Clinical Consulting Services are offered for the purpose of optimizing the
effectiveness and clinical utility of the Device.
- Finally, the Clinical Consulting Services are offered for the purpose of achieving the clinical
outcomes on which the value-based pricing adjustment is based, through process improvement
recommendations, and education of physicians on best practices, among other things.

Finally, the Arrangement meets the criteria listed above to qualify for protection under the proposed safe
harbor, based on the existence and terms of the purchase agreement between the Manufacturer and the
Hospitals.

Therefore, the provision of the $75,000 rebate if the employed physicians’ ADRs do not improve as
intended, the sharing of reimbursement incentive payments due to increased ADRs, and the
Manufacturer’s provision of Clinical Consulting Services and Efficiency Consulting Services and
Solutions would each qualify for protection under the proposed value-based pricing arrangements safe
harbor.

B. PROPOSED VALUE-BASED WARRANTIES SAFE HARBOR

Two of these same aspects of the Arrangement—the provision of the $75,000 rebate if the employed
physicians’ ADRs do not improve as intended and the Manufacturer’s provision of Clinical Consulting
Services—would also qualify for protection under the proposed value-based warranties safe harbor under
a similar analysis.

The proposed value-based warranties safe harbor protects “value-based warranty remedies” (including
“warranty price adjustments”) and “value-based services” offered by a seller of “warranted items” to a
buyer in connection with a value-based warranty, provided that (as applicable to this Arrangement):

- The terms and conditions of the warranty remedy are fixed and disclosed in writing at or in
advance of the time of purchase;
- The value-based services to be provided are identified in writing and disclosed to the buyer at or
in advance of the time of purchase;
The buyer reports to Federal health care programs the price it paid (i.e., its net cost) if and as required by statute, regulation, demonstration or contract (accounting for any warranty price adjustment or allocation of value among components of a bundle);

The buyer does not submit a claim for any value-based services separate and apart from the buyer’s claim for the reimbursable item to which the value-based warranty relates;

The seller does not submit a claim for any value-based services;

The seller assists the buyer in meeting any applicable price reporting obligations to Federal health care programs by providing the value reasonably attributed to the value-based services upon the buyer’s request; and

The seller does not otherwise impede the buyer in meeting any applicable price reporting obligation to Federal health care programs.

The “warranted item” for which payment may be made under a Federal health care program in this Arrangement is the Device.

The definitions of “buyer” and “seller” under the proposed value-based warranties safe harbor are essentially identical to those under the proposed value-based pricing arrangements safe harbor, which the Manufacturer and the Hospitals meet as discussed above.

The Arrangement’s potential $75,000 price reduction constitutes a “warranty price adjustment” and a “value-based warranty remedy” under a “value-based warranty,” as a remedy which is “conditioned and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of the seller’s warranted item purchased or used by the buyer when appropriately used.” Specifically, as was the case under the value-based pricing arrangements safe harbor analysis above, the price adjustment relates to the value of the Device, as reflected in the ADRs achieved—a measurable clinical metric.

The Clinical Consulting Services that are provided by the Manufacturer to the Hospitals meet the proposed value-based warranties safe harbor’s identical definition of “value-based services,” as discussed in detail above.

Finally, the Arrangement meets the criteria listed above to qualify for protection under the proposed value-based warranties safe harbor, based on the existence and terms of the purchase agreement between the Manufacturer and the Hospitals.

IV. ARRANGEMENT PART 2 ANALYSIS

Part 2 of the Arrangement relates to the Efficiency Consulting Services and Solutions component of the bundle. These services and solutions are related to the Device, its servicing, and its consumable components. This aspect of the Arrangement sets an outcome goal of the Hospitals achieving a savings of $X if the recommended processes and solutions are implemented to optimize the supply chain. Under Part 2 of the Arrangement, if the Hospitals save money, then the Manufacturer will be compensated 10% of the savings up to $X and 40% of the savings above $X.

A. PROPOSED VALUE-BASED PRICING ARRANGEMENTS SAFE HARBOR

The proposed value-based pricing arrangements safe harbor protects “value-based price adjustments” and “value-based services” offered by a “seller” to a “buyer” in connection with a “value-based pricing arrangement” (each term as defined in the proposed safe harbor) provided that (as applicable to this Arrangement):

- The terms and conditions of the price adjustment are fixed and disclosed in writing at or in advance of the time of purchase;
The value-based services to be provided are identified in writing and disclosed to the buyer at or in advance of the time of purchase;

The buyer reports to Federal health care programs the price it paid (i.e., its net cost) if and as required by statute, regulation, demonstration or contract (accounting for any price adjustment or allocation of value among components of a bundle);

The buyer does not submit a claim for any value-based services separate and apart from the buyer’s claim for the reimbursable item and/or services included in the value-based pricing arrangement;

The seller does not submit a claim for any value-based services;

The seller assists the buyer in meeting any applicable price reporting obligations to Federal health care programs by providing a reasonable allocation of value among components of the bundle upon the buyer’s request; and

The seller does not otherwise impede the buyer in meeting any applicable price reporting obligation to Federal health care programs.

This second part of the Arrangement meets the definitional aspects of the proposed safe harbor.

First, the Hospitals meet the proposed safe harbor’s definition of “buyer” because they receive reimbursement under Federal health care programs for services they provide to patients. Likewise, the Manufacturer is a “seller” under the proposed safe harbor’s definition because it supplies to buyers (i.e., Hospitals) a reimbursable item—i.e., the Device (reimbursement for which is included in the payment rates set by payors).

The Arrangement’s sharing of any savings as specified in the purchase agreement constitute a “value-based price adjustment” under a “value-based pricing arrangement,” as a price adjustment which are “conditioned and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of the seller’s reimbursable items and/or services purchased by the buyer.” Specifically, the price adjustment here is made by the buyer to the seller of a portion of the amounts which the buyer receives under a payment arrangement [here, the Hospital’s savings] to which the buyer is subject with respect to reimbursable items and/or services as a result (directly or indirectly, wholly or in part) of the intended cost outcome having been achieved (or partially achieved).

The Efficiency Consulting Services and Solutions that are provided by the Manufacturer to the Hospitals meet the proposed safe harbor’s definition of “value-based services” which includes “analysis, software, equipment, information and/or services provided or made available by a seller as part of a value-based pricing arrangement, for no charge apart from the buyer’s price or net cost for the reimbursable items and/or service to which the value-based pricing arrangement relates” for one or more specified purposes. The value-based services provided in connection with Purpose 2 of the Arrangement are offered under the fourth qualifying purpose under the proposed safe harbor for value-based services—to achieve a cost outcome on which the value-based pricing arrangement is based, including through the provision of analysis, software, equipment, information and/or services to patients to facilitate such outcomes.

Finally, the Arrangement meets the criteria listed above to qualify for protection under the proposed safe harbor, based on the existence and terms of the purchase agreement between the Manufacturer and the Hospitals.

Therefore, the provision of the bundled Efficiency Consulting Services and Solutions and the sharing of Hospitals’ savings would each qualify for protection under the proposed value-based pricing arrangements safe harbor.
V. CONCLUSION

We believe that this hypothetical helps to demonstrate why the proposed safe harbors are appropriate. The safe harbors validate the use of pricing adjustments based upon the quality and value of the items and services being purchased, using clinical and/or cost outcome measurements—here, enabling use of higher-quality equipment to detect more pre-cancerous polyps during colonoscopy screening, reducing the development of colon cancer and potentially saving lives. Similarly, bundling reimbursable items and services together with consulting services to optimize the use of the equipment and otherwise achieve and measure the relevant outcomes, for a single price, reflects the reality that achieving the best outcomes often requires more than equipment alone. Ensuring that health care industry buyers and sellers can so condition and adjust the prices they pay and receive, based on quality and value, is clearly beneficial to all stakeholders. Federal programs are protected by ensuring that the price adjustments are appropriately reported, if and to the extent required, and that no additional claims are submitted for the services provided. Further, even without the proposed value-based safe harbors, there is low risk for abuse due to the inherent risk sharing structure of Value-Based Arrangements.
ATTACHMENT A
Reimbursement for Screening Colonoscopies

Background
Under Section 4104 of the Balanced Budget Act of 1997, Medicare Part B provides for coverage of screening colorectal cancer procedures, including:

- Screening colonoscopy for persons at average risk for colorectal cancer every 10 years
- Screening colonoscopy for persons at high risk for colorectal cancer every 2 years. Persons who are at high risk of developing colorectal cancer have one or more of the following:
  - A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;
  - A family history of familial adenomatous polyposis;
  - A family history of hereditary nonpolyposis colorectal cancer;
  - A personal history of adenomatous polyps;
  - A personal history of colorectal cancer; or
  - Inflammatory bowel disease, including Crohn’s Disease, and ulcerative colitis.

Coding
From a coding perspective, there are two basic types of colonoscopies, and different codes apply for Medicare, Medicaid and commercial payors:

1. A screening colonoscopy is provided in the absence of signs or symptoms.
2. A diagnostic colonoscopy is performed due to an abnormal finding, sign or symptom (e.g., abnormal bleeding, diarrhea, etc.).

For Medicare patients, a screening colonoscopy is reported with:

HCPCS code G0105 Colorectal cancer screening; colonoscopy on individual at high risk
HCPCS code G0121 Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk

For Medicare only, if the physician finds an abnormality during the screening colonoscopy, the procedure turns into a diagnostic colonoscopy. When this happens, HCPCS G codes are no longer reported and instead a diagnostic CPT code is reported (CPT code 45378) or an appropriate therapeutic CPT code is reported if a therapeutic procedure is performed (CPT codes 45379 – 45392). Please note that CPT codes from this series include the diagnostic colonoscopy (CPT code 45378) which is not separately reported with the therapeutic CPT code. In addition, when a screening colonoscopy turns into a diagnostic/therapeutic intervention, a modifier –PT must be appended to indicate to Medicare that the procedure started out as a screening procedure.

For Medicaid and Commercial patients, a screening colonoscopy (average or high risk) is reported with a diagnostic CPT code:

CPT code 45378 Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)

5 Although not directly relevant to the Arrangement, the vast majority of colonoscopies are performed under moderate (conscious) sedation. There are various moderate sedation HCPCS and CPT codes that are appropriate to report, depending on the situation. These are time-based codes. The initial base code is for 15 minutes of intra-service time, and each additional period of 15 minutes is reported with an add-on code. Multiple procedure reduction in payment rules do not apply for these conscious sedation procedures.
**Sites of Service**
There are three main sites of service for colonoscopies and associated therapeutic procedures, including the physician office, ambulatory surgery center (ASC) or hospital outpatient setting. Sometimes the procedures are performed in a gastrointestinal endoscopy suite that may bill as a physician office, hospital outpatient department or ASC. Although the Arrangement involves colonoscopies that are performed in a hospital outpatient setting, by physician employees of the Hospitals, the Manufacturer could enter into a similar arrangements with ASCs or physician practices.

**Medicare Payment**
The Medicare payment rates for colonoscopies include all supplies, instruments and equipment costs. For screening colonoscopies (with no therapeutic intervention), there is less than $1 Medicare physician payment differential for high risk and average risk patients. There is no facility differential for high risk and average risk patients. There is no difference in the payment rate if more than one polyp is removed.

Facility payment for conscious sedation is packaged, and there is no separate facility payment. By way of background, the following chart shows the relevant HCPCS codes, CPT codes and 2017 Medicare payment rates by site of service. For screening, diagnostic or therapeutic colonoscopy procedures, there always is a physician payment, and if performed in the facility setting, there is either a payment to the hospital outpatient department or the ambulatory surgery center (ASC). Medicare does not adjust the facility’s reimbursement based on the ADR of the physician performing the service.

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<th>CPT/HCPCS code</th>
<th>Descriptor</th>
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<tr>
<td>G0500</td>
<td>Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older (additional time may be reported with 99153, as appropriate)</td>
<td>$59.22</td>
</tr>
<tr>
<td>45385</td>
<td>Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique</td>
<td>$433.89</td>
</tr>
</tbody>
</table>

---

6 The Arrangement assumes that the Device is not designated as a new technology service and does not qualify for transitional pass-through payment status.

7 In most cases, there is separate physician payment for conscious sedation.
<table>
<thead>
<tr>
<th>CPT/HCPCS code</th>
<th>Descriptor</th>
<th>2017 Medicare National Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Physician Payment (Office)</td>
</tr>
<tr>
<td>99152</td>
<td>Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older</td>
<td>$52.04</td>
</tr>
<tr>
<td>99153</td>
<td>Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes intraservice time (List separately in addition to code for primary service)</td>
<td>$11.13</td>
</tr>
<tr>
<td>99156</td>
<td>Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intraservice time, patient age 5 years or older</td>
<td>N/A</td>
</tr>
<tr>
<td>99157</td>
<td>Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intraservice time (List separately in addition to code for primary service)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
By way of example, the following summarizes how a routine screening colonoscopy of an average risk patient (no signs, symptoms or history of abnormal findings) with polyp removal would be coded and reimbursed under Medicare:

Patient Background:

Patient: 67 year old female, average risk

Payor: Medicare

Site of service: Hospital outpatient setting

Procedure: Patient undergoes a routine screening colonoscopy in the hospital outpatient setting. Patient has no signs, symptoms or history of abnormal findings on previous colonoscopies. During the procedure, a 4 mm polyp is found and removed using a snare technique.

Procedure time: 45 minutes

The original intent of the procedure was to perform a screening colonoscopy on an average risk patient. During the procedure, a polyp was found, so the procedure went from being a typical screening colonoscopy to being a diagnostic colonoscopy with therapeutic procedure. The following are the relevant CPT codes and payment rate for this procedure:

<table>
<thead>
<tr>
<th>CPT/HCPCS code</th>
<th>Descriptor</th>
<th>Physician Payment (Facility)</th>
<th>Hospital Outpatient Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>45385-PT⁸</td>
<td>Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique</td>
<td>$268.45</td>
<td>$877.60</td>
</tr>
<tr>
<td>G0500</td>
<td>Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older (additional time may be reported with 99153, as appropriate)</td>
<td>$5.74 Packaged</td>
<td></td>
</tr>
<tr>
<td>99153</td>
<td>Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes intraservice time (List separately in addition to code for primary service)</td>
<td>$0 Packaged</td>
<td></td>
</tr>
</tbody>
</table>

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⁸ Please note that the payment would not change regardless of whether the patient was average or high risk for colorectal cancer.

⁹ A PT modifier is appended to the code to indicate that this procedure began as a screening test. Medicare will still waive the deductible, but the patient will be responsible for the coinsurance.
<table>
<thead>
<tr>
<th>CPT/ HCPCS code</th>
<th>Descriptor</th>
<th>Physician Payment (Facility)</th>
<th>Hospital Outpatient Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>99153</td>
<td>Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes intraservice time (List separately in addition to code for primary service)</td>
<td>$0</td>
<td>Packaged</td>
</tr>
<tr>
<td></td>
<td>Total Estimated Medicare Payment</td>
<td>$274.19</td>
<td>$877.60</td>
</tr>
</tbody>
</table>

The estimated Medicare payment would be the same regardless of whether the payment was average risk or high risk for colorectal cancer.