H.R. _____

To modernize the safe harbors under the federal Anti-Kickback Statute and the Civil Monetary Penalty Rules Regarding Beneficiary Inducements to promote value-based arrangements.

IN THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES

introduced the following bill: which was referred to the Committee on ___________________

A BILL

To modernize the safe harbors under the federal Anti-Kickback Statute and the Civil Monetary Penalty Rules Regarding Beneficiary Inducements to promote value-based arrangements.

1 Be it enacted by the Senate and House of Representa-

tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the [“____________

5 ____________ Act of 2021”].
SEC. 2. [TBD].

(a) IN GENERAL.—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

(1) in subsection (b)(3)(J) by striking “and” after the semicolon at the end;

(2) in subsection (b)(3)(K) by striking the period at the end and inserting a semicolon; and

(3) by inserting after subsection (b)(3)(K) the following new subparagraphs:

“(L) any value-based price adjustment or value-based services provided in connection with a value-based pricing arrangement pursuant to the following, as applicable—

“(i) The terms and conditions of the value-based price adjustment are fixed and disclosed in writing by the seller or buyer making such value-based price adjustment available, at or prior to the time of the buyer’s first purchase or coverage of the seller’s reimbursable items and/or services (as defined in subparagraph (L)(v)(III) of this subsection) under the value-based pricing arrangement. For such purposes, terms and conditions shall be deemed fixed if the formula or other objective mechanism for determining the amount of the value-based price adjustment is set forth in such written document.

“(ii) The value-based services to be provided or made available by the seller as part of such value-based pricing arrangement are identified in writing and disclosed by the seller to the buyer at or prior to the time of the buyer’s first purchase or coverage of reimbursable items and/or services under the value-based pricing arrangement; provided, that with respect to value-based services described in
subparagraph (L)(v)(IV)(aa), such value-based services shall instead be identified in writing and disclosed by the seller to the buyer at or prior to the time they are provided.

“(iii) In the case of the buyer:

“(I) If and as required under any applicable Federal health care program statute, regulation, demonstration or contract pursuant to which such buyer furnishes or provides coverage for the reimbursable items and/or services to which such value-based pricing arrangement relates, the buyer appropriately reports and/or reflects the buyer’s price and/or net cost for the reimbursable items and/or services to which the value-based pricing arrangement relates, taking into account (aa) any such value-based price adjustment provided to or by the buyer as part of such value-based pricing arrangement, and (bb) the value reasonably attributed by the seller to each reimbursable item and/or service provided or made available by the seller as part of such value-based pricing arrangement, as provided by the seller under subparagraph (L)(iv) below; and

“(II) The buyer does not submit a claim for separate payment for any value-based services provided or made available by the seller under the value-based pricing arrangement apart from the buyer’s claim which includes the reimbursable items and/or services included in the value-based pricing arrangement.

“(iv) In the case of a seller:
“(I) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under subparagraph (L)(iii) of this subsection, such seller provides the buyer the value reasonably attributed by the seller to each reimbursable item and/or service provided by the seller under the value-based pricing arrangement;

“(II) The seller does not submit a claim or otherwise seek reimbursement under any Federal health care program for any reimbursable items and/or services or value-based services which it provides or makes available as part of the value-based pricing arrangement, apart from its reimbursement under such value-based pricing arrangement; and

“(III) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under subparagraph (L)(iii) of this subsection.

“(v) For purposes of this subparagraph (L):

“(I) The term buyer means (aa) an individual or entity (such as a provider or supplier) which receives reimbursement under any Federal health care program for reimbursable items and/or services furnished by such person or entity, and (bb) an entity (such as a Medicare Advantage organization or a Medicare Part D plan sponsor) which provides coverage and reimbursement for reimbursable items and/or services and is fully or partially at risk for the
cost of such reimbursable items and/or services (other than on a fee-for-service basis);

“(II) The term seller means an individual or entity which supplies to a buyer, either directly or indirectly through one or more intermediaries (such as a wholesaler), one or more reimbursable items and/or services and makes available a value-based price adjustment to the buyer, is the recipient of a value-based price adjustment made available by the buyer to the seller, and/or makes available one or more value-based services to or for the benefit of such buyer or its patients (in each case, subject to the terms and conditions of the value-based pricing arrangement);

“(III) The term reimbursable items and/or services means items and/or services for which payment may be made, in whole or in part, under a Federal health care program;

“(IV) The term value-based services means analysis, software, equipment, information and/or services provided or made available by a seller as part of a value-based pricing arrangement, for a reduced charge or no charge (apart from the buyer's price or net cost for the reimbursable items and/or services to which the value-based pricing arrangement relates), reasonably necessary or appropriate for one or more of the following purposes:

“(aa) Determining the terms of such value-based pricing arrangement before such
terms are fixed and disclosed in writing
(including, without limitation, determining
one or more of the metrics to be used in the
value-based pricing arrangement);

“(bb) Measuring, collecting, calculating
and/or reporting the metric(s) upon which the
value-based pricing arrangement is based
and/or the resulting value-based price
adjustment (if any) which is payable;

“(cc) Optimizing the effectiveness and
clinical utility of the reimbursable items
and/or services to which the value-based
pricing arrangement relates (e.g., training
and/or process improvements); and/or

“(dd) Otherwise achieving the clinical
and/or cost outcomes on which the value-
based pricing arrangement is based,
including through provision of analysis,
software, equipment, information and/or
services to patients to facilitate such
outcomes;

Provided, that in the case of value-based
services described in items (cc) and (dd) of this
definition, such services must meaningfully
contribute to efforts to achieve clinical and/or cost
outcomes in connection with conditions diagnosed or
treated by one or more reimbursable items and/or
services to which the value-based pricing
arrangement relates, or to the use of one or more
such reimbursable items and/or services (including,
but not limited to, avoiding potential adverse outcomes related to such condition, diagnosis, treatment or use), in each case when such reimbursable items and/or services are appropriately used, and which do not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer’s patients.

“(V) The term value-based pricing arrangement means an agreement or other arrangement under which a seller provides a value-based price adjustment to a buyer, a buyer provides a value-based price adjustment to a seller, and/or a seller makes available value-based services, in each case in accordance with the requirements of this section:

“(VI) The term value-based price adjustment means a reduction to or increase in a buyer’s price or net cost for one or more reimbursable items and/or services supplied by a seller under a value-based pricing arrangement, consisting of:

“(aa) a discounted or bundled price or net cost initially payable by a buyer for one or more such reimbursable items and/or services, as set forth in the written document referenced in subparagraph (L)(i) of this subsection, as part of a value-based pricing arrangement which also includes terms and conditions for a value-based price adjustment provided in accordance with item (bb) of this definition and/or value-based services
provided in accordance with items (cc) or (dd) of the definition of such term; and/or

“(bb) a payment made by a seller to a buyer, or to a buyer by a seller, as a reduction to or increase in the buyer’s price or net cost for one or more such reimbursable items and/or services, 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 reimbursable items and/or services purchased by such buyer under such value-based pricing arrangement when appropriately used, and which does not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer’s patients, in accordance with terms and conditions set forth in the written document referenced in subparagraph (L)(i) of this subsection.

Without limitation of the foregoing, a value-based price adjustment under this subparagraph (L)(v)(VI) may include, without limitation, (AA) the seller’s payment to a buyer of all or a portion of amounts which the buyer owes or fails to receive under a payment arrangement to which the buyer is subject with respect to reimbursable items and/or services, or of costs otherwise borne by the buyer, as a result (directly or indirectly,
wholly or in part) of the intended clinical and/or cost outcome not having been achieved (or only partially achieved), or (BB) the buyer’s payment to the seller of all or a portion of amounts which the buyer receives under a payment arrangement 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 clinical and/or cost outcome having been achieved (or partially achieved).

“(M) any value-based warranty remedy or value-based services provided by a seller of warranted items to a buyer of such warranted items in connection with a value-based warranty, pursuant to the following, as applicable—

“(i) The terms and conditions of the value-based warranty remedy are fixed and disclosed in writing by the seller making such value-based warranty available, at or prior to the time of the buyer’s first purchase or coverage of the seller’s warranted items to which the value-based warranty relates.

“(ii) The value-based services to be provided or made available by the seller as part of such value-based warranty are identified in writing and disclosed by the seller to the buyer at or prior to the time of the buyer’s first purchase or coverage of the warranted items to which the value-based warranty relates; provided, that with respect to value-based services described in subparagraph (M)(v)(III)(aa), such value-based services shall instead be identified in
writing and disclosed by the seller to the buyer at or prior to the time they are provided.

“(iii) In the case of the buyer:

“(I) If and as required under any applicable Federal health care program statute, regulation, demonstration or contract pursuant to which such buyer furnishes or provides coverage for the warranted items to which such value-based warranty relates, the buyer appropriately reports and/or reflects the buyer’s price and/or net cost for the warranted items to which the value-based warranty relates, taking into account (aa) any warranty price adjustment (as defined in subparagraph (L)(v)(VII) of this section) and (bb) the value reasonably attributed by the seller to each reimbursable item and/or service provided or made available by the seller as part of such value-based warranty, as provided by the seller under subparagraph (M)(iv) below;

“(II) The buyer does not report or reflect any cost for any warranty replacement items and/or services (as defined in subparagraph (M)(v)(VIII) of this section) provided as part of a value-based warranty remedy under any Federal health care program, or otherwise seek reimbursement under any Federal health care program for such warranty replacement items and/or services; and

“(III) The buyer does not submit a claim for separate payment for any value-based services provided or made available by the seller under the
value-based warranty apart from the buyer’s claim which includes the warranted items to which the value-based warranty relates.

“(iv) In the case of the seller:

“(I) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under subparagraph (M)(iii) of this section, such seller provides the buyer the value reasonably attributed by the seller to each reimbursable item and/or service provided by the seller under the value-based warranty;

“(II) Such seller does not submit a claim or otherwise seek reimbursement under any Federal health care program for any such value-based warranty remedy or value-based services provided or made available by it as part of the value-based warranty; and

“(III) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under subparagraph (M)(iii) of this section.

“(v) For purposes of this subparagraph (M):

“(I) The term buyer means (aa) a Federal health care program beneficiary who receives a warranted item under a Federal health care program, (bb) an individual or entity (such as a provider or supplier) which receives reimbursement under any Federal health care program for a warranted item provided or supplied by such person or entity and (cc) an entity (such as a Medicare
Advantage organization or a Medicare Part D plan sponsor) which provides coverage and reimbursement for a warranted item and is fully or partially at risk for the cost of such warranted item (on other than a fee for service basis):

“(II) The term seller means an individual or entity which supplies or provides to a buyer, either directly or indirectly through one or more intermediaries (such as a wholesaler), one or more warranted items with respect to which such seller makes available a value-based warranty remedy to the buyer (subject to the terms and conditions of the value-based warranty), and may also make available one or more value-based services to or for the benefit of such buyer or its patients:

“(III) The term value-based services means analysis, software, equipment, information and/or services provided or made available by a seller as part of a value-based warranty, for a reduced charge or no charge (apart from the buyer’s price or net cost for the warranted items to which the value-based warranty relates), reasonably necessary or appropriate for one or more of the following purposes:

“(aa) Determining the terms of such value-based warranty before such terms are fixed and disclosed in writing (including, without limitation, determining one or more of the metrics to be used in the value-based warranty);
“(bb) Measuring, collecting, calculating and/or reporting the metric(s) upon which the value-based warranty is based and/or the resulting value-based warranty remedy (if any) which is to be provided thereunder;

“(cc) Optimizing the effectiveness and clinical utility of the warranted items being provided or supplied by the seller under the value-based warranty (e.g., training and/or process improvements); and/or

“(dd) Otherwise achieving the clinical and/or cost outcomes which, if not achieved, would trigger a value-based warranty remedy under the value-based warranty, including through provision of analysis, software, equipment, information and/or services to patients to facilitate such outcomes;

Provided, that in the case of value-based services described in items (cc) and (dd) of this definition, such services must meaningfully contribute to efforts to achieve clinical and/or cost outcomes in connection with conditions diagnosed or treated by one or more reimbursable items and/or services to which the value-based pricing arrangement relates, or to the use of one or more such reimbursable items and/or services (including, but not limited to, avoiding potential adverse outcomes related to such condition, diagnosis, treatment or use), in each case when such reimbursable items and/or services are
appropriately used, and which do not knowingly
induce the buyer to reduce or limit medically
necessary items or services to the buyer's patients:

“(IV) The term value-based warranty means
an agreement or other arrangement under which a
seller makes available one or more value-based
warranty remedies to a buyer, conditioned upon
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 such buyer when appropriately used, and
which does not knowingly induce the buyer to reduce
or limit medically necessary items or services to the
buyer's patients:

“(V) The term value-based warranty remedy
means a warranty price adjustment and/or warranty
replacement items and/or services provided by a
seller to a buyer under a value-based warranty, in
accordance with the terms and conditions of such
value-based warranty:

“(VI) The term warranted items means items
for which payment may be made, in whole or in part,
under a Federal health care program, which are
manufactured, supplied and/or provided by a seller,
and for which such seller makes available any value-
based warranty remedy under a value-based
warranty:

“(VII) The term warranty price adjustment
means a payment made by a seller to a buyer (other
than a Federal health care program beneficiary) as a reduction to such buyer's price or net cost for one or more warranted items under a value-based warranty. A warranty price adjustment under this subparagraph (M)(v)(VII) may include, without limitation, the seller's payment to a buyer of all or a portion of amounts which the buyer owes or fails to receive under a payment arrangement to which the buyer is subject with respect to warranted items, or of costs otherwise borne by the buyer, as a result (directly or indirectly, wholly or in part) of the intended clinical and/or cost outcome not having been achieved (or only partially achieved): and

“(VIII) The term warranty replacement items and/or services means (aa) one or more items supplied or provided to a buyer (including, but not limited to, a Federal health care program beneficiary) by a seller (or by a third party at a seller’s expense) to replace or supplement a warranted item, and/or (bb) medical, surgical, hospital or other services and related items provided to a buyer by a seller (or by a third party at a seller’s expense) in connection with the replacement or supplementation of a warranted item or as an alternative or supplemental treatment to the use of the warranted item, provided the following requirements are met: (AA) such items and/or services are supplied, provided and/or paid for in accordance with the terms and conditions of the value-based warranty; (BB) such items and/or
services are not billed by any person to any Federal health care program; and (CC) such items and/or services are medically appropriate.

“(N) any transfer of value provided under a Value-Based Risk Sharing Arrangement pursuant to the following, as applicable—

“(i) A Value-based Risk-Sharing Arrangement is a written agreement under which participants agree to:

“(I) Contribute to the achievement of pre-identified and measurable clinical and/or economic target endpoints that are specifically designed to promote improved patient outcomes and/or reduction of the costs of health care delivery, while avoiding negatively affecting patient outcomes;

“(II) Implement associated processes and procedures that seek to optimize the delivery, efficiency, and/or quality of patient-centered care; and

“(III) Assume an allocation of the financial risk in achieving the targeted endpoints and/or outcomes, with consideration of the participants’ respective contributions thereto.

Under this subsection, remuneration shall also not include participant activities reasonably necessary or appropriate to determine the terms of such Value-Based Risk-Sharing Arrangement before such terms are set forth in a written agreement (including, without limitation, determining one or more of the metrics to be used in the Value-Based Risk-Sharing Arrangement) or measure, collect, calculate and/or report the metric(s) upon which the Value-Based Risk-Sharing Arrangement is based and/or
the resulting economic benefit and/or exposure. The activities to determine the terms of a Value-based Risk-Sharing Arrangement shall be identified in writing and disclosed between the participants at or prior to the time such activities take place.

For purposes of this clause, financial risk is defined as the economic benefit and/or exposure that each participant agrees to assume with regard to the other participant(s) and the amount of which is subsequently calculated with reference to a specified methodology, which benefits or exposures may include shared savings payments, underachievement payments, withholds, bonuses, and/or the like. The methodology to determine financial risk must be set forth in writing and in advance of the performance of the specific Risk-Sharing Arrangement and shall not be dependent upon the volume or value of any referrals or the purchase of any participant’s goods or services which do not contribute to the achievement of pre-identified clinical and/or economic target metrics.

“(ii) A transfer of value may be exchanged between or among one or more participants under a Value-Based Risk Sharing Arrangement that is intended to:

“(I) Drive or promote accountability for quality, cost, coordination, and overall care of patient populations, including patient populations that receive services that are reimbursed by different methodologies and/or by different payors; or
“(II) Manage and coordinate care for patients through arrangements approved by the entities in the arrangement and administered, furnished, or arranged by such entities; or

“(III) encourage efficient deployment and utilization of infrastructure and/or facilitate redesign or care process workflow to achieve higher quality and/or more efficient service delivery for patients, where efficient service delivery includes, among other things, redeployment of and training on the use of goods and services, appropriate reduction of costs or more optimal utilization of goods and services provided to patients, and/or expanded access to healthcare choices to patient populations (including previously underserved populations), in each case consistent with quality of care, physician medical judgment, and patient freedom of choice.”

SEC. 3. CONFORMING EDITS.

[TBD]