

[Discussion Draft]

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-*
2 *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".

1 **SEC. 2. [TBD].**

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

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

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

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

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

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

24 “(ii) The value-based services to be provided or made
25 available by the seller as part of such value-based pricing
26 arrangement are identified in writing and disclosed by the
27 seller to the buyer at or prior to the time of the buyer’s first
28 purchase or coverage of reimbursable items and/or services
29 under the value-based pricing arrangement; provided, that
30 with respect to value-based services described in

1 subparagraph (L)(v)(IV)(aa), such value-based services
2 shall instead be identified in writing and disclosed by the
3 seller to the buyer at or prior to the time they are provided.

4 “(iii) In the case of the buyer:

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

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

30 “(iv) In the case of a seller:

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“(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

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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

1 terms are fixed and disclosed in writing
2 (including, without limitation, determining
3 one or more of the metrics to be used in the
4 value-based pricing arrangement);

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

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

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

22 Provided, that in the case of value-based
23 services described in items (cc) and (dd) of this
24 definition, such services must meaningfully
25 contribute to efforts to achieve clinical and/or cost
26 outcomes in connection with conditions diagnosed or
27 treated by one or more reimbursable items and/or
28 services to which the value-based pricing
29 arrangement relates, or to the use of one or more
30 such reimbursable items and/or services (including,

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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

1 provided in accordance with items (cc) or (dd)
2 of the definition of such term; and/or

3 “(bb) a payment made by a seller to a
4 buyer, or to a buyer by a seller, as a reduction
5 to or increase in the buyer’s price or net cost
6 for one or more such reimbursable items
7 and/or services, which is conditioned and/or
8 calculated based upon one or more clinical
9 and/or cost outcomes (determined using one
10 or more measurable metrics) which are
11 associated with the value of the seller’s
12 reimbursable items and/or services purchased
13 by such buyer under such value-based pricing
14 arrangement when appropriately used, and
15 which does not knowingly induce the buyer to
16 reduce or limit medically necessary items or
17 services to the buyer’s patients, in accordance
18 with terms and conditions set forth in the
19 written document referenced in
20 subparagraph (L)(i) of this subsection.

21 Without limitation of the foregoing, a value-
22 based price adjustment under this
23 subparagraph (L)(v)(VI) may include, without
24 limitation, (AA) the seller’s payment to a
25 buyer of all or a portion of amounts which the
26 buyer owes or fails to receive under a payment
27 arrangement to which the buyer is subject
28 with respect to reimbursable items and/or
29 services, or of costs otherwise borne by the
30 buyer, as a result (directly or indirectly,

1 wholly or in part) of the intended clinical
2 and/or cost outcome not having been achieved
3 (or only partially achieved), or (BB) the
4 buyer’s payment to the seller of all or a
5 portion of amounts which the buyer receives
6 under a payment arrangement to which the
7 buyer is subject with respect to reimbursable
8 items and/or services as a result (directly or
9 indirectly, wholly or in part) of the intended
10 clinical and/or cost outcome having been
11 achieved (or partially achieved).

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

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

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

1 writing and disclosed by the seller to the buyer at or prior
2 to the time they are provided.

3 “(iii) In the case of the buyer:

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

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

28 “(III) The buyer does not submit a claim for
29 separate payment for any value-based services
30 provided or made available by the seller under the

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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

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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);

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“(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

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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

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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

1 services are not billed by any person to any Federal
2 health care program; and (CC) such items and/or
3 services are medically appropriate.

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

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

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

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

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

22 Under this subsection, remuneration shall also not
23 include participant activities reasonably necessary or
24 appropriate to determine the terms of such Value-Based
25 Risk-Sharing Arrangement before such terms are set forth
26 in a written agreement (including, without limitation,
27 determining one or more of the metrics to be used in the
28 Value-Based Risk-Sharing Arrangement) or measure,
29 collect, calculate and/or report the metric(s) upon which the
30 Value-Based Risk-Sharing Arrangement is based and/or

1 the resulting economic benefit and/or exposure. The
2 activities to determine the terms of a Value-based Risk-
3 Sharing Arrangement shall be identified in writing and
4 disclosed between the participants at or prior to the time
5 such activities take place.

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

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

24 “(I) Drive or promote accountability for
25 quality, cost, coordination, and overall care of
26 patient populations, including patient populations
27 that receive services that are reimbursed by
28 different methodologies and/or by different payors;
29 or

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“(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]