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MEMORANDUM

TO: Clients and Friends

FROM: Craig Holden, Kristin Bohl and Derrick Godfrey

DATE: November 14, 2018

RE: Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

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The new Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, signed into law on October 24, 2018, contains a number of provisions aimed at addressing the opioid crisis. Section 8121 thereof is separately referred to as the Eliminating Kickbacks in Recovery Act of 2018 (the "Act") and contains a provision (to be codified at 18 U.S.C. § 220) that prohibits the payment of remuneration for referrals to certain providers. Much like other healthcare fraud and abuse laws, the Act contains a general prohibition followed by a list of exceptions. The Attorney General, in consultation with the Secretary of Health and Human Services, is permitted to promulgate regulations to clarify the exceptions.

The Act prohibits any person, with respect to services covered by a health care benefit program, from paying, offering to pay, soliciting or receiving any remuneration (1) to induce a referral of an individual to a recovery home, clinical treatment facility, or a laboratory or (2) in exchange for an individual using the services of a recovery home, clinical treatment facility or a laboratory. The Act does not offer a specific definition of "remuneration," so presumably the definition would be the same or substantially similar to the broad definition provided in the federal Anti-Kickback Statute ("AKS"), which includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

Importantly, the Act applies to kickbacks related to services covered by a "health care benefit program," which is defined as "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." The definition of health care benefit program sets the Act apart from other notable federal health care fraud and abuse laws in that it applies to services reimbursable by private insurers and not just governmental insurance programs. Because of that, it is likely that the Act applies to virtually all substance abuse treatment facilities and laboratories.

Referrals relating to three types of providers whose involvement triggers application of the Act include: (1) recovery homes, (2) clinical treatment facilities, and (3) laboratories. The definition of each type of provider is below:

> ***Recovery Home*** means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.
>
> ***Clinical Treatment Facility*** means a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law.
>
> ***Laboratory*** means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

The broad definition of the types of entities covered means that the Act has application beyond opioid-related treatment (or even other substance abuse treatment). ***Any*** referrals to these types of entities are potentially implicated, whether opioid related or not.

There are eight exceptions to the general prohibition. No interpretative guidance has yet been issued, but AKS guidance is instructive. Each exception is discussed below.

(1) **a discount or other reduction in price obtained by a provider of services or other entity under a health care benefit program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity;**

- This discount exception is broad and mirrors the statutory discount exception in the AKS.

(2) **a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by —**

(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
(B) the number of tests or procedures performed; or
(C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

- This exception is broader than the comparable AKS exception for payments to bona fide employees in that it specifically protects payments made pursuant to independent contractor arrangements. At the same time, it is far narrower than the AKS employment exception in that it bans any remuneration to employed or contracted sales personnel based on the volume

or value of referrals. Therefore, any commission-based structure is problematic. The AKS employment exception clearly permitted such commission structures.

(3) **a discount in the price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program under section 1860D–14A(g) of the Social Security Act (42 U.S.C. 1395w–114a(g));**

- This exception is intended to account solely for a discount offered in compliance with another law, so it likely has no applicability outside of the cross-referenced statute.

(4) **a payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of section 1001.952(d) of title 42, Code of Federal Regulations, as in effect on the date of enactment of this section;**

- The exception for payments to contractors is co-extensive with the similar safe harbor under the AKS. Of course, the Act applies to private insurers, so arrangements specifically tailored to carve out governmental business would still be implicated by the Act.

(5) **a waiver or discount (as defined in section 1001.952(h)(5) of title 42, Code of Federal Regulations, or any successor regulation) of any coinsurance or copayment by a health care benefit program if—**

(A) the waiver or discount is not routinely provided; and

(B) the waiver or discount is provided in good faith;

- This is coextensive with the cross-referenced section of the AKS, except that it incorporates the additional requirements that the waiver or discount be not routinely provided and provided in good faith. These additional requirements are found elsewhere in the AKS regulations, though they are not specifically tied to the cross-referenced safe harbor.

(6) **a remuneration described in section 1128B(b)(3)(I) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)(I));**

- This exception deals with certain payments from a health center related to services provided in a medically underserved area. It is unlikely to have general application to the providers targeted by the Act.

(7) **a remuneration made pursuant to an alternative payment model (as defined in section 1833(z)(3)(C) of the Social Security Act) or pursuant to a payment arrangement used by a State, health insurance issuer, or group health plan if the Secretary of Health and Human Services has determined that such arrangement is necessary for care coordination or value-based care; or**

(8) **any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation.**

- These exceptions will have limited application, except that the exceptions may be expanded by regulation promulgated in the future.

The Act explicitly states that the kickback section neither supersedes the AKS nor preempts similar state laws. However, the Act clearly and explicitly goes beyond the AKS in certain ways--e.g., less protection for employment relationships and additional safeguards on certain discounts. Therefore, unless these additional safeguards were an unintended oversight, it is very likely that the purpose of the Act is to be more restrictive than the AKS both in its application to payments from private payors and in its more restrictive exceptions.

Annotated Version of the Act

"§ 220. Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories."

"(a) Offense.—Except as provided in subsection (b), whoever, with respect to services covered by a **health care benefit program**,[1] in or affecting interstate or foreign commerce, knowingly and willfully—

(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a **recovery home**,[2] **clinical treatment facility**,[3] or **laboratory**;[4] or

(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

(B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

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1 "means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."

2 means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

3 means a medical setting , other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law.

4 has the meaning given the term in section 353 of the Public Health Service Act (42 U.S.C. 263a - "As used in this section, the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.")

shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

(b) Applicability.—Subsection (a) shall not apply to—

(1) a discount or other reduction in price obtained by a provider of services or other entity under a health care benefit program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity;

(2) a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—

(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
(B) the number of tests or procedures performed; or
(C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

(3) a discount in the price of an **applicable drug**[5] of a manufacturer that is furnished to an **applicable beneficiary**[6] under the Medicare coverage gap discount program under section 1860D–14A(g) of the Social Security Act (42 U.S.C. 1395w–114a(g));

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5 The term "applicable drug" means, with respect to an applicable beneficiary, a covered part D drug--

(A) approved under a new drug application under section 355(b) of Title 21 or, in the case of a biologic product, licensed under section 262 of this title (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 262 of this title); and

(B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;

(ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or

(iii) is provided through an exception or appeal.

6 The term "applicable beneficiary" means an individual who, on the date of dispensing a covered part D drug--

(A) is enrolled in a prescription drug plan or an MA-PD plan;

(B) is not enrolled in a qualified retiree prescription drug plan;

(C) is not entitled to an income-related subsidy under section 1395w-114(a) of this title; and

(D) who--

(4) a payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of section 1001.952(d) of title 42, Code of Federal Regulations,[7] as in effect on the date of enactment of this section;

(5) a waiver or discount (as defined in section 1001.952(h)(5)[8] of title 42, Code of Federal Regulations, or any successor regulation) of any coinsurance or copayment by a health care benefit program if—

(A) the waiver or discount is not routinely provided; and

(B) the waiver or discount is provided in good faith;

(6) a remuneration described in section 1128B(b)(3)(I) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)(I)[9]);

(7) a remuneration made pursuant to an alternative payment model (as defined in section 1833(z)(3)(C) of the Social Security Act[10]) or pursuant to a payment arrangement used by a State, health insurance issuer, or group health plan if the Secretary of Health and Human Services has determined that such arrangement is necessary for care coordination or value-based care; or

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(i) has reached or exceeded the initial coverage limit under section 1395w-102(b)(3) of this title during the year; and

(ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1395w-102(b)(4)(B) of this title.

7 Attached.

8 Attached.

9 "any remuneration between a health center entity described under clause (i) or (ii) of section 1396d(l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity. . ."

10 (3) Additional definitions.— In this subsection:

. . .

(C) Alternative payment model (apm).— The term `alternative payment model' means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1115A (other than a health care innovation award).

(ii) The shared savings program under section 1899.

(iii) A demonstration under section 1866C.

(iv) A demonstration required by Federal law.

(8) any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation."

(c) Regulations.—The Attorney General, in consultation with the Secretary of Health and Human Services, may promulgate regulations to clarify the exceptions described in subsection (b).

(d) Preemption.—

(1) FEDERAL LAW.—This section shall not apply to conduct that is prohibited under section 1128B of the Social Security Act (42 U.S.C. 1320a–7b).

(2) STATE LAW.—Nothing in this section shall be construed to occupy the field in which any provisions of this section operate to the exclusion of State laws on the same subject matter.

(e) Definitions.—In this section—

(1) the terms ‘applicable beneficiary’ and ‘applicable drug’ have the meanings given those terms in section 1860D–14A(g) of the Social Security Act (42 U.S.C. 1395w–114a(g));

(2) the term ‘clinical treatment facility’ means a medical setting , other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law;

(3) the term ‘health care benefit program’ has the meaning given the term in section 24(b);

(4) the term ‘laboratory’ has the meaning given the term in section 353 of the Public Health Service Act (42 U.S.C. 263a); and

(5) the term ‘recovery home’ means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

42 C.F.R. § 1101.952(d).

(d) Personal services and management contracts. As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic, or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

42 C.F.R. § 1101.952(h).

(h) Discounts. As used in section 1128B of the Act, "remuneration" does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section.

…

(5) For purposes of this paragraph, the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term discount does not include—

(i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;

(iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.