NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. SHAPOUR MOTAMEDI, Defendant-Appellant, and SHAYAN MOTAMEDI, Defendant, HERIBERTO MOISES LOPEZ, Defendant.	No. 20-10364 D.C. Nos. 3:18-cr-00554-WHA-1 3:18-cr-00554-WHA MEMORANDUM* (Filed Jan. 11, 2022)

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. SHAYAN MOTAMEDI, Defendant-Appellant, and	No. 20-10366 D.C. Nos. 3:18-cr-00554-WHA-2 3:18-cr-00554-WHA

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

SHAPOUR MOTAMEDI;
HERIBERTO MOISES LOPEZ,
Defendants.

UNITED STATES OF AMERICA,
Plaintiff-Appellee,
v.
HERIBERTO MOISES LOPEZ,
Defendant-Appellant,
and
SHAPOUR MOTAMEDI;
SHAYAN MOTAMEDI,
Defendants.

No. 20-10367

D.C. Nos.
3:18-cr-00554-WHA-3
3:18-cr-00554-WHA

Appeal from the United States District Court
for the Northern District of California
William Alsup, District Judge, Presiding

Argued and Submitted December 10, 2021
San Francisco, California

Before: WARDLAW, BRESS, and BUMATAY, Circuit Judges.
Concurrence by Judge BUMATAY

Shapour Motamedi, Shayan Motamedi, and Heriberto Moises Lopez (collectively "Defendants") pleaded guilty to conspiracy to violate 42 U.S.C. § 1320a-7b(b), the "Anti-Kickback Statute." On appeal, they argue that their convictions should be vacated

because a subsection of the Anti-Kickback Statute known as the "Safe Harbor Provision," 42 U.S.C. § 1320a-7b(b)(3)(E), violates the non-delegation doctrine. We have jurisdiction under 28 U.S.C. § 1291, and we affirm their convictions.

1. The Safe Harbor Provision provides that the Secretary of Health and Human Services (HHS) may specify by regulation payment practices to which the "illegal remunerations" prohibitions shall not apply. 42 U.S.C. § 1320a7b(b)(3)(E). Thus, the Safe Harbor Provision delegates to the Secretary the ability to remove certain types of conduct from the scope of the offense defined by statute. Given the combined operation of the Anti-Kickback Statute and the Safe Harbor Provision, we conclude that Defendants are challenging their statute of conviction and thus have standing to assert their non-delegation argument.

2. The delegation in the Safe Harbor Provision is constitutional, however, because Congress has supplied HHS with an "intelligible principle" to guide the Secretary's discretion in setting those bounds.[1] *United*

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[1] Defendants argue that that we should dispense with the traditional "intelligible principle test" for determining whether a statute violates the non-delegation doctrine, and adopt the stricter test proposed by Justice Gorsuch in his dissent in *United State v. Gundy*, 139 S. Ct. 2116, 2129, *reh'g denied*, 140 S. Ct. 579 (2019). However, as the Defendants acknowledge, "[w]e are bound to follow a controlling Supreme Court precedent until it is explicitly overruled by that Court," and the intelligible principle test remains the standard for determining whether the delegation of legislative power is constitutional. *Nunez-Reyes v. Holder*, 646

States v. Gundy, 139 S. Ct. 2116, 2123 (plurality op.), *reh'g denied*, 140 S. Ct. 579 (2019). Under modern precedent, the intelligible principle test imposes "an exceedingly modest limitation." *United States v. Melgar-Diaz*, 2 F.4th 1263, 1266 (9th Cir. 2021); *see also Gundy*, 139 S. Ct. at 2129 (plurality op.) (explaining that the intelligible principle test is "not demanding"). For example, the Supreme Court has upheld the delegation of broad conferrals of authority to regulate "in the public interest," *National Broadcasting Co. v. United States*, 319 U.S. 190, 216 (1943), to set "fair and equitable prices," *Yakus v. United States*, 321 U.S. at 422, 427 (1944), to set "just and reasonable rates," *FPC v. Hope Natural Gas Co.*, 320 U.S. 591 (1944), and to issue air quality standards that are "requisite to protect the public health." *Whitman v. American Trucking Association*, 531 U.S. 457 (2001).

In this case, the instructions Congress provided to HHS are much more specific than the instructions the Supreme Court has upheld against non-delegation challenges. Congress gave the Secretary a list of nine factors to consider when promulgating exceptions to the criminal prohibition under the Safe Harbor Provision. *See* 42 U.S.C. § 1320a-7d(a)(2). Those nine factors direct the Secretary to consider whether adding a safe harbor would improve the quality of healthcare in the United States in general by doing things like improving "access to healthcare services," improving the "quality of health care services," and reducing

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F.3d 684, 692 (9th Cir. 2011); *see also Miller v. Gammie*, 335 F.3d 889, 893 (9th Cir. 2003) (en banc).

incentives for doctors to "overutiliz[e]" healthcare services. *Id.* The delegation in the Safe Harbor Provision is, therefore, constitutional.

Defendants make two arguments in response, neither of which has merit. First, they argue that whatever guidance Congress provided in 42 U.S.C. § 1320a7d(a)(2) is vitiated by the catchall section, § 1320a-7d(a)(2)(I), which permits the Secretary to consider "[a]ny other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs (as so defined)." They contend that this "catchall clause" allows the Secretary to consider anything she wants, so her discretion isn't cabined at all.

We disagree. For one, even considered in isolation, § 1320a-7d(a)(2)(I) provides an intelligible principle to guide the Secretary's discretion. The Secretary is directed to consider "other factors" to the extent that they serve the interest of preventing "fraud and abuse in Federal health care programs." 42 U.S.C. § 1320a7d(a)(2)(I). That instruction reflects an intelligible principle: it is possible to evaluate whether a particular safe harbor promulgated by the Secretary is likely to prevent fraud and abuse or not. And again, that direction, even standing alone, is more stringent a guardrail than guidelines the Court has upheld in the past, such as regulating "in the public interest," *National Broadcasting Co.*, 319 U.S. at 216, or setting "just and reasonable" rates, *Hope Natural Gas Co.*, 320 U.S. at 591.

Defendants also argue that even if 42 U.S.C. § 1320a-7d(a)(2) provides sufficient guidance in the context of a civil statute, Congress should be required to provide more guidance in the context of a criminal statute, relying on *Touby v. United States*, 500 U.S. 160 (1991). However, there, the Supreme Court said only that its case law was "not entirely clear as to whether more specific guidance is in fact required" in the context of a criminal statute, declining to resolve that question because the statute at issue "passe[d] muster even if greater congressional specificity is required in the criminal context." *Id.* at 166. Similarly here, we need not decide that question because, as discussed above, Section 7d(a)(2) clearly provides an intelligible principle which passes muster "even if greater congressional specificity is required in the criminal context." *Id.*

AFFIRMED.

United States v. Motamedi, et al., Nos. 20-10364, 20-10366, 20-10367
BUMATAY, Circuit Judge, concurring:

I agree we should affirm the Appellants' convictions here, but I would do so without reaching the merits of their non-delegation claim. I thus concur in the judgment of the court only.

The Appellants were convicted of conspiracy to violate 42 U.S.C. § 1320a7b(b)—the Anti-Kickback Statute. *See* 18 U.S.C. § 371. The Anti-Kickback

Statute makes it a felony to receive or pay kickbacks, bribes, or rebates in return for purchasing "any item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1), (b)(2). The Statute, however, establishes various safe harbors to criminal liability. *See* 42 U.S.C. § 1320a-7b(b)(3). One of those safe harbors invites the Secretary of Health and Human Services to promulgate regulations exempting certain "payment practice[s]" from criminal liability under the Statute. 42 U.S.C. § 1320a-7b(b)(3)(E).

In yet another law, Congress provided criteria to HHS for establishing and modifying these safe harbors. 42 U.S.C. § 1320a-7d(a)(2). This law set out eight relatively specific factors for HHS to consider in adopting or amending a safe harbor regulation. *See* 42 U.S.C. § 1320a-7d(a)(2)(A)–(H). But the law ends with what's been called a "catchall provision"—permitting HHS to consider "[a]ny other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs." 42 U.S.C. § 1320a-7d(a)(2)(I). It is here that the Appellants complain.

Appellants contend that this catchall provision grants HHS almost unfettered authority to decide which actions are criminal under the Anti-Kickback Statute with no meaningful congressional guidance. They claim that such a provision violates the non-delegation doctrine as traditionally understood, *see Mistretta v. United States*, 488 U.S. 361, 372 (1989), and especially under the robust non-delegation view articulated by Justice Gorsuch, *see Gundy v. United States*,

139 S. Ct. 2116, 2131 (2019) (Gorsuch, J., dissenting). They then ask us to reverse their convictions based on the violation of the non-delegation doctrine.

There's one problem with that: Assuming they are right—that the catchall provision provides no "intelligible principle" and thus Congress has unconstitutionally delegated its authority to HHS—the catchall provision is easily severable from the Anti-Kickback Statute. "Unless it is evident that the legislature would not have enacted those provisions which are within its power, independently of that which is not, the invalid part may be dropped if what is left is fully operative as law." *United States v. Taylor*, 693 F.2d 919, 921–22 (9th Cir. 1982) (quoting *United States v. Jackson*, 390 U.S. 570, 585 (1968)). Given the text, structure, and chronological development of the Anti-Kickback Statute and the safe harbor regulations, I find it unlikely that Congress would have chosen to discard the entire law prohibiting kickbacks if it could not also include the catchall provision for establishing safe harbors. *See id.* at 922.

So even if we were to strike the catchall provision as a violation of the non-delegation doctrine, the rest of the Anti-Kickback Statute would remain fully operative and Appellants' convictions under § 1320a-7b(b) and 18 U.S.C. § 371 would be untouched. *Id.* I thus join the majority in affirming their convictions.

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. SHAPOUR MOTAMEDI, Defendant-Appellant, and SHAYAN MOTAMEDI, Defendant, HERIBERTO MOISES LOPEZ, Defendant.	No. 20-10364 D.C. Nos. 3:18-cr-00554-WHA-1 3:18-cr-00554-WHA Northern District of California, San Francisco ORDER (Filed Feb. 23, 2022)

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. SHAYAN MOTAMEDI, Defendant-Appellant, and SHAPOUR MOTAMEDI; HERIBERTO MOISES LOPEZ, Defendants.	No. 20-10366 D.C. Nos. 3:18-cr-00554-WHA-2 3:18-cr-00554-WHA Northern District of California, San Francisco

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. HERIBERTO MOISES LOPEZ, Defendant-Appellant, and SHAPOUR MOTAMEDI; SHAYAN MOTAMEDI, Defendants.	No. 20-10367 D.C. Nos. 3:18-cr-00554-WHA-3 3:18-cr-00554-WHA

Before: WARDLAW, BRESS, and BUMATAY, Circuit Judges.

The panel has unanimously voted to deny the petition for rehearing en banc. The full court has been advised of the petition and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing en banc is DENIED.

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

United States Constitution, Article I, Section 1

All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.

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42 U.S.C. § 1320a-7b

(a) Making or causing to be made false statements or representations. Whoever—

> (1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)),
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> (2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,
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> (3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment

> either in a greater amount or quantity than is due or when no such benefit or payment is authorized,
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> (4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,
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> (5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or
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> (6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under title XIX [42 USCS §§ 1396 et seq.], if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c) [42 USCS § 1396p(c)],

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any other person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $100,000 or imprisoned for not more than 10 years or both, or (ii) in the

case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $20,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b) Illegal remunerations.

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

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

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such

individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1861(u) [42 USCS § 1395x(u)]), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of title XVIII [42 USCS §§ 1395j et seq.] by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act;

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 [note to this section] or in regulations under section 1860D-3(e)(6) [1860D-4(e)(6)] [42 USCS § 1395w-104(e)(6)];

(F) any remuneration between an organization and an individual or entity providing items or services, or a

combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 [42 USCS § 1395mm] or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of title XVIII [42 USCS §§ 1395w-101 et seq.], if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) [42 USCS § 1320a7a(i)(6)(A)] are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D-14(a)(3) [42 USCS § 1395w-114(a)(3)]), section 1128A(i)(6)(A) [42 USCS § 1320a-7a(i)(6)(A)] shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4) [42 USCS § 1395w-23(a)(4)];

(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1905(1)(2)(B) [42 USCS § 1396d(1)(2)(B)] 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;

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1860D-14A(g) [42 USCS § 1395w-114a(g)]) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D-14A [42 USCS § 1395w-114a]; and

> (K) an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1899 [42 USCS § 1395jjj(m)], if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.
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> (4) Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under title XVIII, title XIX, or title XXI [42 USCS §§ 1395 et seq., 1396 et seq., 1397aa et seq.] shall be imprisoned for not more than 10 years or fined not more than $500,000 ($1,000,000 in the case of a corporation), or both.

(c) False statements or representations with respect to condition or operation of institutions. Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity (including an eligible

organization under section 1876(b) [42 USCS § 1395mm(b)]) for which certification is required under title XVIII [42 USCS §§ 1395 et seq.] or a State health care program (as defined in section 1128(h) [42 USCS § 1320a-7(h)]), or with respect to information required to be provided under section 1124A [42 USCS § 1320a-3a], shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(d) Illegal patient admittance and retention practices. Whoever knowingly and willfully—

> (1) charges, for any service provided to a patient under a State plan approved under title XIX [42 USCS §§ 1396 et seq.], money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under title XIX under a contract under section 1903(m) [42 USCS § 1396b(m)] or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or
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> (2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under title XIX [42 USCS §§ 1396 et seq.], any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)—

(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(e) Violation of assignment terms. Whoever accepts assignments described in section 1842(b)(3)(B)(ii) [42 USCS § 1395u(b)(3)(B)(ii)] or agrees to be a participating physician or supplier under section 1842(h)(1) [42 USCS § 1395a(h)(1)] and knowingly, willfully, and repeatedly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $4,000 or imprisoned for not more than six months, or both.

(f) "Federal health care program" defined. For purposes of this section, the term "Federal health care program" means—

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States

Government (other than the health insurance program under chapter 89 of title 5, United States Code [5 USCS §§ 8901 et seq.]); or

(2) any State health care program, as defined in section 1128(h) [42 USCS § 1320a-7(h)].

(g) Liability under subchapter III of chapter 37 of title 31. In addition to the penalties provided for in this section or section 1128A [42 USCS § 1320a-7a], a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code [31 USCS §§ 3721 et seq.].

(h) Actual knowledge or specific intent not required. With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

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42 U.S.C. § 1320a-7d

(a) Solicitation and publication of modifications to existing safe harbors and new safe harbors.

(1) In general.

(A) Solicitation of proposals for safe harbors. Not later than January 1, 1997, and not less than annually thereafter, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for—

(i) modifications to existing safe harbors issued pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 (42 U.S.C. 1320a-7b note);

(ii) additional safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) [42 USCS § 1320a-7b(b)] and shall not serve as the basis for an exclusion under section 1128(b)(7) [42 USCS § 1320a-7(b)(7)];

(iii) advisory opinions to be issued pursuant to subsection (b); and

(iv) special fraud alerts to be issued pursuant to subsection (c).

(B) Publication of proposed modifications and proposed additional safe harbors. After considering the proposals described in clauses (i) and (ii) of subparagraph (A), the Secretary, in consultation with the Attorney General, shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors, if

appropriate, with a 60-day comment period. After considering any public comments received during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors, as appropriate.

(C) Report. The Inspector General of the Department of Health and Human Services (in this section referred to as the "Inspector General") shall, in an annual report to Congress or as part of the year-end semiannual report required by section 5 of the Inspector General Act of 1978 (5 U.S.C. App.), describe the proposals received under clauses (i) and (ii) of subparagraph (A) and explain which proposals were included in the publication described in subparagraph (B), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

(2) Criteria for modifying and establishing safe harbors. In modifying and establishing safe harbors under paragraph (1)(B), the Secretary may consider the extent to which providing a safe harbor for the specified payment practice may result in any of the following:

(A) An increase or decrease in access to health care services.

(B) An increase or decrease in the quality of health care services.

(C) An increase or decrease in patient freedom of choice among health care providers.

(D) An increase or decrease in competition among health care providers.

(E) An increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

(F) An increase or decrease in the cost to Federal health care programs (as defined in section 1128B(f) [42 USCS § 1320a-7b(f)]).

(G) An increase or decrease in the potential overutilization of health care services.

(H) The existence or nonexistence of any potential financial benefit to a health care professional or provider which may vary based on their decisions of—

> (i) whether to order a health care item or service; or
>
> (ii) whether to arrange for a referral of health care items or services to

a particular practitioner or provider.

(I) Any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs (as so defined).

(b) Advisory opinions.

(1) Issuance of advisory opinions. The Secretary, in consultation with the Attorney General, shall issue written advisory opinions as provided in this subsection.

(2) Matters subject to advisory opinions. The Secretary shall issue advisory opinions as to the following matters:

(A) What constitutes prohibited remuneration within the meaning of section 1128B(b) [42 USCS § 1320a-7b(b)] or section 1128A(i)(6) [42 USCS § 1320a-7a(i)(6)].

(B) Whether an arrangement or proposed arrangement satisfies the criteria set forth in section 1128B(b)(3) [42 USCS § 1320a-7b(b)(3)] for activities which do not result in prohibited remuneration.

(C) Whether an arrangement or proposed arrangement satisfies the criteria which the Secretary has established, or shall establish by

regulation for activities which do not result in prohibited remuneration.

(D) What constitutes an inducement to reduce or limit services to individuals entitled to benefits under title XVIII or title XIX [42 USCS §§ 1395 et seq. or 1396 et seq.] within the meaning of section 1128A(b) [42 USCS § 1320a-7a(b)].

(E) Whether any activity or proposed activity constitutes grounds for the imposition of a sanction under section 1128, 1128A, or 1128B [42 USCS § 1320a-7, 1320a-7a, or 1320a-7b].

(3) Matters not subject to advisory opinions. Such advisory opinions shall not address the following matters:

(A) Whether the fair market value shall be, or was paid or received for any goods, services or property.

(B) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986 [26 USCS § 3121(d)(2)].

(4) Effect of advisory opinions.

(A) Binding as to secretary and parties involved. Each advisory opinion issued by the Secretary shall be

binding as to the Secretary and the party or parties requesting the opinion.

(B) Failure to seek opinion. The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections [section] 1128, 1128A, or 1128B [42 USCS § 1320a-7, 1320a-7a, or 1320a-7b].

(5) Regulations.

(A) In general. Not later than 180 days after the date of the enactment of this section [enacted Aug. 21, 1996], the Secretary shall issue regulations to carry out this section. Such regulations shall provide for—

(i) the procedure to be followed by a party applying for an advisory opinion;

(ii) the procedure to be followed by the Secretary in responding to a request for an advisory opinion;

(iii) the interval in which the Secretary shall respond;

(iv) the reasonable fee to be charged to the party requesting an advisory opinion; and

(v) the manner in which advisory opinions will be made available to the public.

(B) Specific contents. Under the regulations promulgated pursuant to subparagraph (A)—

(i) the Secretary shall be required to issue to a party requesting an advisory opinion by not later than 60 days after the request is received; and

(ii) the fee charged to the party requesting an advisory opinion shall be equal to the costs incurred by the Secretary in responding to the request.

(6) Application of subsection. This subsection shall apply to requests for advisory opinions made on or after the date which is 6 months after the date of enactment of this section [enacted Aug. 21, 1996].

(c) Special fraud alerts.

(1) In general.

(A) Request for special fraud alerts. Any person may present, at any time, a request to the Inspector General for a notice which informs the public of practices which the Inspector General considers to be suspect or of

particular concern under the Medicare program under title XVIII [42 USCS §§ 1395 et seq.] or a State health care program, as defined in section 1128(h) [42 USCS § 1320a-7(h)] (in this subsection referred to as a "special fraud alert").

(B) Issuance and publication of special fraud alerts. Upon receipt of a request described in subparagraph (A), the Inspector General shall investigate the subject matter of the request to determine whether a special fraud alert should be issued. If appropriate, the Inspector General shall issue a special fraud alert in response to the request. All special fraud alerts issued pursuant to this subparagraph shall be published in the Federal Register.

(2) Criteria for special fraud alerts. In determining whether to issue a special fraud alert upon a request described in paragraph (1), the Inspector General may consider—

(A) whether and to what extent the practices that would be identified in the special fraud alert may result in any of the consequences described in subsection (a)(2); and

(B) the volume and frequency of the conduct that would be identified in the special fraud alert.