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COMMISSION AUTHORIZED

COMMENTS OF THE FEDERAL TRADE COMMISSION'S BUREAUS OF COMPETITION, CONSUMER PROTECTION AND ECONOMICS

CONCERNING THE DEVELOPMENT OF REGULATIONS PURSUANT TO THE MEDICARE AND MEDICAID ANTI-KICKBACK STATUTE

PRESENTED TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

(LRR-17-NI)

DECEMBER 18, 1987

I. Introduction

Congress has directed the Secretary of Health and Human Services ("the Secretary") to "promulgate . . . regulations, specifying payment practices that shall not be treated as a criminal offense"[1] under the Medicare and Medicaid anti-kickback law, Section 1128B(b) of the Social Security Act,[2] and that shall not provide a basis for excluding providers from the Medicare or Medicaid programs under Section 1128(b)(7).[3] The staff of the Federal Trade Commission[4] is pleased to provide these comments in response to the Department of Health and Human Services' request for public comments before proposed regulations are published by the Secretary.[5] We urge the Secretary to adopt regulations that make clear that those involved in certain types of legitimate, pro-competitive arrangements -- which can produce cost savings for the Medicare and Medicaid programs or for the programs' patients -- are not considered to be in violation of Section 1128B(b)'s broadly worded prohibition of referral fees.

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[1] Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 680, 697 (1987).

[2] 42 U.S.C. § 1320a-7b(b). Section 1128B of the Social Security Act consolidates what were Sections 1877 (Medicare anti-kickback provision) and 1909 (Medicaid anti-kickback provision) of the Social Security Act, 42 U.S.C. §§ 1395nn and 1396h. Pub. L. No. 100-93, § 4.

[3] 42 U.S.C. § 1320a-7(b)(7).

[4] These comments represent the views of the Federal Trade Commission's Bureaus of Competition, Consumer Protection, and Economics, and not necessarily those of the Commission itself or of any individual Commissioner. The Commission has, however, voted to authorize their submission.

[5] 52 Fed. Reg. 38,794 (Oct. 19, 1987).

III. Interest and Experience of the Federal Trade Commission

Our interest in this matter stems from our involvement in competition and consumer protection policy. The Federal Trade Commission is empowered under 15 U.S.C. § 41 et seq. to prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. Pursuant to this statutory mandate, the Commission encourages competition among members of the licensed professions to the maximum extent compatible with other state and federal goals. For more than a decade, the Commission has investigated the competitive effects of restrictions on the business arrangements of hospitals and state-licensed health professionals, including physicians, pharmacists, physical therapists, and others. Among the restrictions that we have examined are ones that, like Section 1128B(b), prohibit the payment of rebates and referral fees.[6] Our goal has been to identify and seek the removal of those restrictions that impede competition, increase costs, and harm consumers without providing substantial countervailing benefits.

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[6] Letter from Janet M. Grady, Regional Director, San Francisco Regional Office, Federal Trade Commission to Hon. Chuck Hardwick, Speaker of the Assembly of the State of New Jersey (May 21, 1987); Letter from Walter T. Winslow, Acting Director, Bureau of Competition, Federal Trade Commission to H. Fred Varn, Executive Director, Florida Board of Dentistry (Nov. 6, 1985); Letter from Walter T. Winslow, Acting Director, Bureau of Competition, Federal Trade Commission to George M. Sanchez, O.D., President, Arizona State Board of Optometry (Oct. 17, 1985). Copies of these letters are available from the Federal Trade Commission's Office of Public Affairs.

IV. The Medicare/Medicaid Anti-Kickback Statute and its Purpose

The Medicare and Medicaid anti-kickback statute provides that a person is guilty of a felony (1) whenever he knowingly 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 an individual for goods or services covered by Medicare or Medicaid or in return for purchasing or arranging the purchase of such goods or services, or (2) whenever he knowingly offers or pays any remuneration to induce such referral or purchase.[7]

Congress adopted the original version of this provision in 1972, and made violation of it a felony in 1977, in large part because it determined that the condemned practices "contribute significantly to the cost of the [Medicare and Medicaid] programs."[8] A concern is that kickbacks can encourage fraudulent referrals for unnecessary care. According to Congress, this type of fraudulent practice

> cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government-sponsored program. It diverts from those most in need, the nation's elderly and poor, scarce program dollars that

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[7] Section 1128B(b) of the Social Security Act, 42 U.S.C § 1320a-7b(b).

[8] H.R. Rep. No. 95-393 (II), 91st Cong., 1st Sess., reprinted in 1977 U.S. Code Cong. & Ad. News 3039, 3055.

were intended to provide vitally needed quality health services.[9]

V. Arrangements That Should Not Be Considered in Violation

In connection with our efforts to promote competition in the health care sector of the economy, we have observed several types of business arrangements and practices that could be construed to violate Section 1128B(b), but which we believe are pro-competitive, and in many cases are likely to help control Medicare and Medicaid costs. These include business arrangements involving HMOs, PPOs, and referral services, and business practices such as the referral of patients by providers to health care facilities owned by the providers and hospital waiver of Medicare copayments and deductibles. We explain below how each of these types of arrangements and practices could be construed to violate Section 1128B(b), and why, nonetheless, they are pro-competitive, and may benefit third-party payors such as Medicare and Medicaid. Although we are not aware of any prosecutions under Section 1128B(b) of providers involved in these types of arrangements and practices, we are concerned that some people may be discouraged from using pro-competitive arrangements because of

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[9] Id. at 3047.

the severe penalties to which violators of Section 1128B(b) are subject.[10]

A. Alternative Health Care Delivery Systems

Health maintenance organizations and preferred provider organizations are health care delivery systems that are marketed to employers, unions, and other groups as alternatives to traditional fee-for-service programs offered by third-party payors such as commercial health insurers. We believe that alternative delivery systems can be pro-competitive forces in the health care market.[11] For example, both HMOs and PPO programs typically have built-in incentives to control health care costs and thus provide cost-effective alternatives to traditional systems for the financing and delivery of health care.[12] In

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[10] Violators are subject to a maximum of five years in prison and a $25,000 fine, 42 U.S.C. § 1320a-7b(b), and exclusion from participation as providers in the Medicare and Medicaid programs, 42 U.S.C. § 1320a-7(b)(7).

[11] See, e.g., Health Care Management Associates, 101 F.T.C. 1014 (1983) (advisory opinion concerning PPO program); Letter from James C. Miller III, Chairman, Federal Trade Commission, to Representative Ron Wyden (July 29, 1983) (commenting favorably on proposed federal legislation which would have exempted PPOs from the coverage of certain state laws and regulations).

[12] See e.g., Epstein, Begg and McNeil, The Use of Ambulatory Testing in Prepaid and Fee-for-Service Group Practices, 314 N. Engl. J. Med. 1089 (1986); Johnson and Aquilina, The Impact of Health Maintenance Organizations and Competition on Hospitals in Minneapolis/St. Paul, 10 J. of Health Politics, Policy and Law 659 (1986); Bureau of Economics, Federal

addition, as "bulk" purchasers of hospital and medical services, HMOs and PPOs can increase competition among providers of such services, who vie for contracts with them.

Although they exist in many different forms, all PPO programs involve a series of contractual arrangements between "preferred" health care providers and an intermediary, such as an insurer or self-insured employer, that acts as a third-party payor of health care benefits. PPO programs often attempt to select preferred providers for their ability to deliver quality health care at a low cost. Enrollees in PPO programs usually are given financial incentives, typically waivers of copayments and deductibles, to encourage them to use these lower cost preferred providers.

HMOs are similar, in many respects, to PPO programs. Both types of arrangements use a limited panel of health care providers and provide coverage for a wide range of health care services. HMOs differ from PPO programs in that HMOs deliver these services directly to enrollees by employing or contracting with health care providers, as well as by undertaking the insurance function that third-party payors provide in PPO arrangements. In addition, HMOs generally provide coverage only if enrollees obtain their health care services from these

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Trade Commission, Staff Report on the Health Maintenance Organization and Its Effects on Competition (1977).

participating providers. Most PPO programs, by contrast, provide coverage for use of non-participating providers, albeit at a higher out-of-pocket cost to enrollees.

Some of the contractual arrangements used by HMO and PPO programs, however, may involve legitimate payments that nevertheless could be construed to violate Section 1128B(b). For example, some PPO programs require participating providers to remit to the PPO a percentage of the fees earned from treating PPO patients. This is one method used for funding a PPO's administrative expenses. Although not all PPOs are financed in this manner, this type of PPO program may be attractive to many providers because the fees they pay to the PPO are directly proportional to the benefits (i.e., the number of referred patients) that they receive from participating in the program. Because the financial success of a new program often is uncertain, providers may prefer to participate in such PPO programs that "meter" the benefits to them rather than in programs that require substantial up-front capital contributions or annual charges. On its face, this type of financial arrangement might be characterized as a payment by the provider of a "kickback" to the PPO program in order to induce the PPO to refer patients to the provider, in violation of Sections 1128B(b)(1)(A) and (2)(A)[13] if Medicare or Medicaid funds are involved.

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[13] 42 U.S.C. §§ 1320a-7b(b)(1)(A) and (2)(A).

Certain financial arrangements used by HMOs could also be construed to violate Section 1128B(b). For example, some HMOs, particularly those known as the IPA (individual practice association) type, hold back a certain percentage of each individual provider's fees for services rendered, in order to create a reserve to pay for an unexpectedly high use of services by the entire subscriber population. This "holdback" fund is later distributed pro rata to the providers if the program's aggregate utilization levels, and hence its costs, do not exceed the anticipated levels upon which the HMO's premiums were based. This arrangement is used to spread some of the HMO's financial risk over its participating providers, and gives providers an additional incentive to help control unnecessary use of expensive health care services. The distribution of the holdback fund could be considered the payment of a rebate in violation of Section 1128B(b).

We believe, however, that these types of HMO and PPO arrangements are unlikely to increase payments by the Medicare and Medicaid programs[14] because such arrangments do not provide incentives for making referrals for unnecessary or inappropriate medical care. For example, the PPO program described above,

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[14] We understand that Medicare currently contracts with HMOs to provide health care to some of the program's patients, 42 U.S.C. § 1395mm, and that it also is considering using PPO arrangements to provide care to patients.

while perhaps technically making a referral and receiving a fee in return, does not itself suggest or recommend medical care. The PPO program provides only a list of preferred health care providers, from which patients can choose. Thus, the PPO program is not in a position to refer patients for unnecessary care in order to increase the amount of fees paid to the PPO by providers. Furthermore, the physician or other health care provider who actually recommends medical care to a PPO patient does not receive any referral fee under the arrangement we have described. For the same reasons, the HMO "holdback" arrangement described above is unlikely to result in unnecessary referrals and higher costs to the Medicare and Medicaid programs. Indeed, rather than encouraging referrals for unnecessary care, the holdback, which providers do not receive if program costs exceed anticipated levels, encourages providers to hold down costs and thus conserve program resources.

Use of alternative delivery systems such as HMOs and PPOs can actually reduce the costs of third-party payors, such as Medicare and Medicaid. Most HMO and PPO programs are designed to control health care costs so that the programs can be successfully marketed to cost-conscious groups. The programs that are likely to succeed in the increasingly price-competitive health care industry are those that best help employers,

insurers, and other third-party payors cut health care costs.[15] HMOs and PPOs typically attempt to control costs in several ways. First, many HMO and PPO programs are "bulk" purchasers of medical services and are often able to negotiate fees that are lower than providers' usual charges. Second, PPO programs often seek to contract with providers who have demonstrated a propensity to control expenditures. Third, many PPOs and HMOs use innovative methods to control costs, such as risk-sharing among providers and incentives for enrollees to use preferred providers. Finally, many HMO and PPO programs provide strict controls on utilization.

We believe that the contractual payments made to HMOs and PPOs that we have described above should be analyzed in the context of the overall cost-saving potential of the programs of which they are a part. This is very similar to the approach taken by Congress in 1986, when it decided to exempt from Section 1128B(b) what otherwise might be construed as "kickbacks" made by vendors to group purchasing agents, as long as certain disclosure and other requirements are met.[16] Congress found that "to cover costs," group purchasing organizations (GPOs) acting on behalf of

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[15] Contracts between HMO and PPO programs and employers, for example, are often subject to renewal or cancellation on an annual basis. Those programs that fail to keep costs down are at risk of losing these contracts to other, more efficient, health care plans.

[16] Section 1128B(b)(3)(C) of the Social Security Act, 42 U.S.C. § 1320a-7b(b)(3)(C).

participating hospitals and other organizations sometimes "require vendors from whom they purchase services or supplies to pay them a fixed percentage of the value of the business that they refer to the vendors."[17] In recommending that such payments be exempt from Section 1128B(b), the House Budget Committee stated:

> The Committee believes that GPO's can help reduce health care costs for the government and the private sector alike by enabling a group of purchasers to obtain substantial volume discounts on the prices they are charged. The Committee understands that the amount of the price reductions exceeds the fees the vendors must pay the GPO's. The Committee can see no justification for prohibiting such cost-saving arrangements . . . .[18]

Thus, Congress determined that the GPOs, when examined in the context of their overall effect on the market, are likely to reduce health care costs. As we have stated, the overall structure of PPOs and HMOs can also help reduce health care costs for the government and the private sector. Payment mechanisms used to cover the costs of PPO programs and HMOs, like the percentage payment system used by GPOs, should be permitted in order to encourage cost-saving arrangements.

In order to encourage the development of programs like HMOs and PPOs that are likely to reduce costs, increase consumer welfare, and benefit the Medicare and Medicaid programs, we urge

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[17] H.R. Rep. No. 99-727, 99th Cong., 2nd Sess., reprinted in 1986 U.S. Code Cong. & Admin. News 3607, 3662.

[18] Id. at 3663.

that the Secretary specifically state, in the proposed regulations, that participation in HMO and PPO programs will not be considered to violate Section 1128B(b).

B. Referral Services

Referral services, which can be either for-profit or not-for-profit, refer prospective patients to one or more providers, based on the stated needs of the patients and the qualifications or prices of the providers. These services could also be construed to violate Section 1128B(b) if providers are required to pay a fee to the service for referrals. However, we believe that referral services are also unlikely to raise the costs of the Medicare and Medicaid programs.

Referral services typically make available a wide variety of information on the providers to whom they refer patients. Such information can promote competition by enabling patients to compare fees and services offered by providers. For example, a referral service can inform patients as to which providers will accept Medicare assignment. The fees paid to referral services are unlikely to provide an incentive for anyone to refer patients for unnecessary care. This is because, like the PPO arrangement described earlier, the entity receiving the fee, the referral service in this case, does not recommend or suggest that the

patient obtain medical care. Indeed, referral services are most often used by patients who "self-refer;" that is, patients who have decided on their own to seek medical care.

For these reasons, we urge the Secretary specifically to state, in the proposed regulations, that participation in referral services will not be considered to violate Section 1128B(b).

C. Ownership Interests

Referral of patients by a provider to an entity in which the provider has a financial interest could also be viewed as a violation of Section 1128B(b). For example, a physician may refer a patient to a laboratory in which he has a partial ownership interest. Presumably, the physician will be entitled to some of the profits generated by the laboratory, some of which may be attributable to that particular referral. Such profits could be construed as "any remuneration . . . [received] directly or indirectly . . . in cash or in kind" in return for referring that patient to that laboratory.[19]

While the benefits of allowing health care practitioners to refer patients to entities in which they have financial interests

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[19] 42 U.S.C. § 1320a-7b(b).

may not be as obvious as those of alternative delivery systems, such practices may have several pro-competitive effects. First, established practitioners in a community might identify particular health care needs in their area, such as, for example, a certain type of medical laboratory. Prohibiting physicians from referring Medicare and Medicaid patients to this laboratory may make them reluctant to invest time, money and experience in such a project.

Second, a practitioner who refers patients for further care to an entity in which he has invested, for example, a physical therapy practice, may be better able to assure continued high quality care for those patients. This is because an investment interest may lead to a stronger, more permanent working relationship between the referring practitioner and the entity in which he has a financial interest.

It can be argued that allowing practitioners to refer patients to entities in which they have financial interests does increase the risk of referrals for unnecessary, inappropriate, or more expensive care. But there are many other common practices in the health care field that also create such a risk that have never been considered to be unlawful. For example, when one practitioner refers a patient to another practitioner in the same professional service corporation or partnership, the referring practitioner will usually share in any profits generated by the

fees paid to the second practitioner.[20] Multispecialty clinics can be a highly efficient way of providing health care services, as can ownership of entities that provide ancillary services. We do not believe that Congress intended to outlaw these practices in the context of the Medicare and Medicaid programs.[21]

The types of practices that could be construed to violate Section 1128B(b) lie on a continuum in terms of their potential to increase the costs of the Medicare and Medicaid programs. At one end of this continuum there are fraudulent "kickbacks" for referrals of Medicare and Medicaid patients, which are illegal. At the other end are situations such as a physician who owns a few shares of stock in a pharmaceutical company. That physician is not likely to be considered in violation of Section 1128B(b) when he prescribes medications manufactured by that company

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[20] This problem may be most evident when a practitioner recommends that he himself provide additional services.

[21] We note that Medicare and Medicaid officials have taken the position that referrals to entities in which the provider has an ownership interest may not violate the law. See Letter from Irv Cohen, Deputy Director, Office of Program Validation, Health Care Financing Administration (Nov. 25, 1980) ("We do not believe that physician referrals to an entity in which the referring physician maintains an ownership (or other investment) interest would, per se, violate the illegal remuneration provisions of section 1877 [predecessor to Section 1128B of the Social Security Act, dealing with Medicare]."); Letter from Martin L. Kappert, Director, Bureau of Quality Control, Health Care Financing Administration (Dec. 10, 1980) (physician's ownership interest in a medical supply company to which the physician may refer his patients does not violate Section 1909 (predecessor to Section 1128B(b) of the Social Security Act, dealing with Medicaid)) (addressees of letters not made public). We beleive, however, that regulations under Section 1128B(b) should make this explicit.

because this practice is unlikely to result in unnecessary prescriptions and thereby increase costs. The problem with which the Secretary is now faced is where to draw the line along this continuum, between those arrangements that should be considered in violation of Section 1128B(b) and those that should not. We believe that the benefits of allowing practitioners to refer patients to health care facilities they own suggest that, in drawing this line, the Secretary should permit such practices.

To reduce the risk of encouraging unnecessary referrals, and to remedy any deception of patients, the Secretary may want to consider adopting regulations under Section 1128B(b) to require that practitioners disclose to patients any ownership interest they have in an entity to which they are referring the patient. Although it is uncertain how much disclosure will reduce Medicare and Medicaid costs, it could provide the patient with information that may aid in the decision whether to use the recommended provider.[22] If a disclosure requirement is adopted, care should be taken to avoid disclosure requirements that impose unnecessary costs on providers.[23]

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[22] Similar disclosure requirements exist in the laws of some states. See, e.g., California Bus. & Prof. Code § 654.2, which requires that physicians disclose in writing to patients any financial interest they have in facilities to which patients are referred, and inform patients that they do not have to use the provider the physician has selected.

[23] The Secretary might also consider regulations that state that Section 1128B(b) will be applied where the percentage of the profits the practitioner receives from the entity in which the

We urge the Secretary specifically to state, in the proposed regulations, that an ordinary return on invested capital will not be considered remuneration within the meaning of Section 1128B(b).

D. Waivers of Deductibles for Medicare Part A

Under Medicare Part A, which provides for payment for inpatient hospital services, Medicare deducts from its payments to hospitals amounts that Medicare permits hospitals to collect from the Medicare patient as coinsurance and deductibles.[24] Some hospitals waive coinsurance and deductible amounts as a marketing technique to attract patients to use their hospitals. Such a waiver could be construed as a payment by the hospital to induce the Medicare patient to use the hospital's

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[24] Apparently, there is no direct statutory requirement that hospitals collect these coinsurance and deductible amounts from patients. Letter from Richard P. Kusserow, Inspector General, U.S. Department of Health and Human Services to Stephen S. Trott, Assistant Attorney General, Criminal Division, U.S. Department of Justice (April 17, 1985).

services, in violation of Section 1128B(b).[25] We believe that waivers of deductible and coinsurance amounts should not be treated as unlawful because they can provide price competition among hospitals. This competition can result in lower prices to Medicare patients and therefore benefit consumers.

Although allowing hospitals to waive these payments may not raise the cost to Medicare for a given hospitalization,[26] overall costs could increase because some patients whose deductible and coinsurance payments are waived by hospitals, will opt for hospitalizations that might not be medically necessary. Congress may have provided for deductible and coinsurance amounts in part to provide incentives for patients to question the advisability of inpatient hospital care.[27]

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[25] See West Allis Memorial Hosp., Inc. v. Bowen, 660 F. Supp. 936 (E.D. Wis. 1987) (preliminary injunction sought by hospital to enjoin competitor hospital's waiver of Medicare deductibles and coinsurance amounts, on grounds that such waiver violated Medicare anti-kickback statute, denied by court).

[26] Hospitals are currently reimbursed by Medicare under a prospective payment system. Pursuant to a specific "diagnosis related group" (DRG) for each patient, hospitals are paid a fixed amount by Medicare regardless of the actual costs incurred by the hospital for treating that particular patient. The hospital is not permitted to bill Medicare for a higher amount to cover the cost of waiving deductibles or coinsurance amounts.

[27] Kusserow, supra, note 24 at 4. However, we understand that the Department of Health and Human Services' Inspector General believes that other mechanisms exist, such as Medicare contracts with quality control peer review organizations, to effectively control overutilization of hospitals. Id. at 5-6.

We suggest that the Secretary consider whether the potential increase in competition and savings to Medicare patients that can occur from waiver of Medicare coinsurance and deductible amounts outweighs the possible overutilization of hospital care that may be caused by such a waiver. If the Secretary determines that the benefits outweigh the costs, then we suggest that the Secretary adopt regulations that make clear that such waivers of Medicare deductibles and coinsurance amounts do not violate Section 1128B(b).[28]

E. Other Arrangements

The specific types of arrangements that we have described are by no means an exhaustive list of the types of arrangements that, although they could be viewed as violating Section 1128B(b), are likely to provide pro-competitive benefits to the

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[28] We note that the Inspector General does not support an exemption for waivers of coinsurance amounts by Medicare Part B providers (providers of medical services other than inpatient hospital services). In part, this is because Part B providers are reimbursed on a fee-for-service basis, with the resulting possibility that the cost of waiving coinsurance amounts may be passed on to the Medicare program. Id. at 4-5. If, in the future, reimbursements to Part B providers are determined on a DRG basis, we suggest that the Secretary follow the same approach regarding waivers by Part B providers that we have outlined regarding Part A providers. In the meantime, the Secretary should consider whether the pro-competitive advantages of allowing Part B providers to waive Medicare deductibles and copayments outweigh the need for criminal sanctions to prevent such providers from passing through the cost of such waivers to the Medicare program.

Medicare and Medicaid programs and their patients. The health care sector of the economy is constantly generating innovative programs that facilitate competition among providers or that are designed to be competitive by controlling costs and providing quality care. There are likely to be additional types of pro-competitive programs, which, like the ones we have described, may contain ancillary financial arrangements that could be construed to violate Section 1128B(b). As long as these ancillary arrangements, when viewed in the context of the pro-competitive programs of which they are a part, are not likely to impose costs on the Medicare and Medicaid programs, including costs for unnecessary care, they should not be prohibited.

We suggest that the Secretary closely examine such arrangements in light of the goals of Section 1128B(b). We urge the Secretary to make clear that if, when balanced against the pro-competitive and cost-saving effects of the entire program, these arrangements are not likely to raise the costs of the Medicare and Medicaid programs, they will not be considered to violate Section 1128B(b).

VI. Conclusion

We have attempted to provide examples of several types of financial arrangements and practices in the health care sector of

the economy that could be construed to violate the Medicare and Medicaid anti-kickback statute, but that are part of pro-competitive health plans or other arrangements that may ultimately provide cost savings to the Medicare and Medicaid programs or to the programs' patients. The specific arrangements we have identified involve HMOs, PPOs, and referral services. The specific practices we have identified include the referral of patients by providers to health care facilities owned by the providers and hospital waiver of Medicare deductibles and coinsurance payments. Many of these arrangements and practices are not likely to raise Medicare and Medicaid costs, and thus are not the type of arrangements and practices that Congress has sought to prohibit. Consequently, we urge the Secretary to develop regulations pursuant to Section 1128B(b) that make clear that providers involved in these and similar financial arrangements and practices that are not likely to raise costs to the Medicare and Medicaid programs, will not be subject to criminal prosecution under Section 1128B(b) and to exclusion from the Medicare and Medicaid programs under Section 1128(b)(7).

We appreciate this opportunity to provide these comments. Please let us know if we can be of any further assistance.