regulation of a drug product under the act. Mr. Kokes was provided 30 days to file objections and request a hearing. Mr. Kokes did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Edwin Kokes has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Edwin Kokes is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)(see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Kokes, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kokes, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Kokes during his period of debarment.

Any application by Mr. Kokes for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N–0539 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 2003.

Steven K. Galson,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 03–10569 Filed 4–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0161]

Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a list (List I) of critical reprocessed single-use devices (SUDs) whose exemption from premarket submission is being terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), is necessary in a premarket notification (510(k)); and a list (List II) of reprocessed SUDs that are currently subject to 510(k) requirements for which FDA has determined that validation data, as specified under MDUFMA, is necessary in a 510(k). FDA is requiring submission of these data to ensure that these reprocessed SUDs are substantially equivalent to predicate devices in accordance with MDUFMA.

DATES: These actions are effective April 30, 2003. Manufacturers of SUDs identified in List I whose exemption is being terminated must submit 510(k)s for these devices by July 30, 2004, or their devices may no longer be marketed. Manufacturers who already have clearance letters for SUDs identified in List II must submit validation data for these devices by January 30, 2004, or marketing of these devices must cease.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments on Lists I and II should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara A. Zimmerman, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA (Pub. L. 107–250), amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this new provision, in order to ensure that reprocessed SUDs are substantially equivalent to predicate devices, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data. These required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Before enactment of the new law, a manufacturer of a reprocessed SUD was required to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt reprocessed SUDs will no longer be exempt from premarket notification requirements. Manufacturers of these identified devices will need to submit 510(k)s that include validation data to be specified by FDA. Reprocessors of certain SUDs that are currently subject to cleared 510(k)s also will need to submit the validation data specified by the agency.

In the near future, FDA will publish a guidance document providing more specific information about the types of validation data that should be submitted in premarket notification submissions for the reprocessed SUDs listed in this notice.

A. Definitions

Under section 302(b) of MDUFMA, a reprocessed SUD is defined as an ''original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.''

B. Reprocessed SUDs Exempt From Premarket Notification

Reprocessed SUDs are divided into three groups: (1) Critical, (2) semicritical, and (3) noncritical. The first two categories reflect definitions set forth in MDUFMA, and all three reflect a classification scheme recognized in

the industry.[1] These categories of devices are defined as follows:

(1) *A critical reprocessed SUD* is intended to contact normally sterile tissue or body spaces during use.

(2) *A semicritical reprocessed SUD* is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(3) *A noncritical reprocessed SUD* is intended to make topical contact and not penetrate intact skin.

1. Requirements for Critical Reprocessed SUDs

MDUFMA requires FDA to review the critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require premarket notification to ensure their substantial equivalence to predicate devices. By April 26, 2003, FDA must identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification will be terminated. List I in this **Federal Register** notice implements this MDUFMA requirement.

In accordance with MDUFMA, manufacturers of the devices identified in List I must submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87 (21 CFR 807.87), within 15 months of publication of this notice or no longer market their device.

2. Requirements for Semicritical Reprocessed SUDs

MDUFMA also requires FDA to review the semicritical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require premarket notification to ensure their substantial equivalence to predicate devices. FDA must identify these devices in a notice published in the **Federal Register** by April 26, 2004. Manufacturers of devices identified at that time will be required to submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance in addition to all the other required elements of a 510(k) identified in § 807.87, within 15 months of publication of that notice or no longer market their device.

[1] Spaulding, E.H., ''The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections,'' P.S. Brachman and T.C. Eickof (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 1971:254–274.

3. Requirements for Noncritical Reprocessed SUDs

MDUFMA does not require FDA to take any action under this section for noncritical SUDs that are exempt from premarket submission requirements.

C. Reprocessed SUDs Already Subject to Premarket Notification Requirements

MDUFMA also requires FDA to review the types of reprocessed SUDs already subject to premarket notification requirements and to identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. FDA must publish a list of these devices in the **Federal Register** by April 26, 2003, and update the list as necessary. List II of this **Federal Register** notice implements this MDUFMA requirement. The devices on List II may be critical, semicritical, or noncritical reprocessed SUDs.

1. For devices identified in List II that have not yet been cleared through the 510(k) process, manufacturers must submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87, upon publication of this notice in order to market these devices. FDA will soon publish guidance to help submitters understand what types of validation data should be included in these 510(k)s.

2. For devices identified in List II that already have been cleared through the 510(k) process, manufacturers must submit validation data regarding cleaning, sterilization, and functional performance within nine months of publication of this notice or marketing must cease. FDA will soon publish guidance to explain how a 510(k) holder may submit the additional data now being required to support an earlier clearance.

II. FDA's Implementation of New Section 510(o) of the Act

FDA used a number of criteria to determine which device types should be included in the lists required by MDUFMA. As part of its consideration, FDA relied upon the Review Prioritization Scheme (RPS) it described in the February 2000 draft guidance document entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme.'' [2] In the RPS guidance, FDA set forth factors that could be used to evaluate risk associated with reprocessed SUDs. This approach assigned an overall risk to each SUD based on: (1) The risk of infection and (2) the risk of inadequate performance following reprocessing. Based on these risk factors, three categories of risk (high, moderate, and low) were developed. The designation of ''high risk'' was assigned to those devices that posed the greatest risk of infection and inadequate performance after reprocessing. In response to several comments about potential subjectivity of the RPS, FDA did not use the RPS approach when the agency finalized its enforcement priorities for reprocessed SUDs on August 14, 2000.

FDA has determined, however, that the RPS is an appropriate risk-based tool for developing the lists required by MDUFMA because the RPS identifies the devices that are likely to raise the most concerns about both infection transmission and inadequate performance following reprocessing. In formulating these lists, the agency also had the benefit of comments from stakeholders and an internal centerwide committee to evaluate the results of the RPS and ensure its consistency. In addition, there was a final review of all the devices on these lists by the Director of the Office of Device Evaluation. In this context, the agency believes these steps have adequately addressed concerns about the subjectivity of the RPS.

In addition to the previous criterion, FDA used one other criterion to identify those reprocessed SUDs that will be subject to the new requirements established by MDUFMA. The agency has included in these lists all reprocessed SUDs intended to come in contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (CJD). These are generally devices intended for use in neurosurgery ophthalmology. This criterion was included in FDA's evaluation because insufficient scientific information exists at this time to establish standard methods to eliminate CJD infectious agents.

Therefore, in order to develop the two lists required by MDUFMA, FDA used the following process. First, the agency identified the types of SUDs that are being reprocessed. FDA did this by searching the 510(k) database for any 510(k)s that had been submitted for reprocessed SUDs and by asking original equipment manufacturers and reprocessors to provide information about types of devices that were being reprocessed. Second, FDA determined whether these devices are ''critical,'' ''semi-critical,'' or ''non-critical''. (These

[2] This draft guidance document is available on the CDRH Web site at *http//www.fda.gov/cdrh/reuse/1156.pdf.*

definitions reflect the Spaulding [3] classification and are the same definitions FDA used earlier in developing its RPS.) FDA then applied the criteria described previously and ''listed'' any reprocessed SUD that was either ''high'' risk according to the RPS or intended to come in contact with tissue at high risk of being infected with the causative agents of CJD.

All devices identified in List I (previously exempt from 510(k)) have been determined to be critical reprocessed SUDs. In addition to being critical, they are either high risk according to the RPS or intended to come in contact with tissue at high risk of being infected with CJD. It should be noted that not all exempt devices that are critical have been listed. Critical reprocessed SUDs that are not listed in List I at this time may be reconsidered in subsequent updates of the list. The devices in List II (devices currently subject to 510(k) requirements that now will require the submission of validation data) are either high risk according to the RPS or intended to come in contact with tissue at high risk of being infected with the causative agents of CJD.

FDA has also provided a reference list in Attachment 1. To show how FDA evaluated the risk of a specific device, Attachment 1 includes the entire group of devices FDA considered when identifying the reprocessed SUDs in Lists I and II, and shows how FDA applied the criteria that determined whether the device would be identified on either of these lists.

In the **Federal Register** of February 4, 2003 (68 FR 5643), FDA invited interested persons to provide information and share views on the implementation of MDUFMA. The agency received several comments that identified specific reprocessed SUDs to be included in Lists I and II. The agency considered these recommendations while finalizing this document. Although FDA's lists do not include all the reprocessed SUDs that were recommended, the agency believes that those devices that pose the greatest risk of infection transmission and inadequate performance have been identified. The agency recognizes, however, that these lists may need to be re-evaluated and updated over time. Therefore, FDA will consider comments from the public on additional devices that should be included in the lists at any time. The agency also notes that MDUFMA permits FDA to request validation data for a device type that is subject to 510(k) clearance but not yet included in List II. If this were to occur, FDA would ensure that manufacturers were aware of this change in the 510(k) submission requirements for that type of device by promptly updating the list.

Finally, FDA received one comment that suggested the agency's prior determinations about risk associated with reprocessed SUDs precluded FDA from now requiring 510(k)s for devices that were previously exempt or additional data for devices that were already cleared. FDA believes that this comment ignores the existence of MDUFMA's requirements. It is true that FDA had initially developed a regulatory approach for reprocessed SUDs that sought to treat those devices and original devices in a similar manner and that FDA had not required additional data to be submitted for certain reprocessed SUDs under that approach. However, through MDUFMA Congress clearly stated its intent to have the agency re-examine its policy with respect to reprocessed SUDs and legislated additional controls for those devices. FDA is committed to fulfilling its responsibilities under MDUFMA. The development and publication of these lists is part of the agency's implementation of these new statutory provisions.

LIST I.—CRITICAL REPROCESSED SINGLE-USE DEVICES PREVIOUSLY EXEMPT FROM PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE 510(K)S WITH VALIDATION DATA

[To be submitted by July 26, 2004]

21 CFR section	Classification name	Product code for Non-reprocessed device	Product code for reprocessed device	Product code name for reprocessed device
872.3240	Dental bur	Diamond Coated	NME	Dental diamond coated bur.
872.4535	Dental diamond instrument	DZP	NLD	Dental diamond instrument.
872.4730	Dental injection needle	DZM	NMW	Dental needle.
874.4140	Ear, nose, and throat bur	Microdebrider	NLY	ENT high speed microdebrider.
874.4140	Ear, nose, and throat bur	Diamond Coated	NLZ	ENT diamond coated bur.
874.4420	Ear, nose, throat manual surgical * * *	KAB, KBG, KCI	NLB	Laryngeal, Sinus, Tracheal trocar.
878.4200	Introduction/drainage catheter and accessories.	GCB	NMT	Catheter needle.
878.4800	Manual surgical instrument	MJG	NNA	Percutaneous biopsy device.
878.4800	Manual surgical instrument	FHR	NMU	Gastro-Urology needle.
878.4800	Manual surgical instrument for * * *	DWO	NLK	Cardiovascular biopsy needle.
878.4800	Manual surgical instrument for * * *	GAA	NNC	Aspiration and injection.
882.4190	Forming/cutting clip instrument	HBS	NMN	Forming/cutting clip instrument.
884.1730	Laparoscopic insufflator * * *	HIF	NMI	Laparoscopic insufflator and accessories.
884.4530	OB/GYN specialized manual instrument	HFB	NMG	Gynecological biopsy forceps.
886.4350	Manual ophthalmic surgical instrument	HNN	NLA	Ophthalmic knife.

[3] Spaulding, E. H., ''The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections,'' P. S. Brachman and T. C. Eickof (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 1971:254–274.

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE THE SUBMISSION OF VALIDATION DATA [1]

[Manufacturers who already have 510(k) clearance for these devices must submit validation data by January 26, 2004. Any new 510(k) will require validation data upon publication of this list.]

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for reprocessed device	Product code name for reprocessed device
Unclassified ..	Oocyte aspiration needles	MHK	NMO	Oocyte aspiration needles.
Unclassified ..	Percutaneous transluminal angioplasty catheter angioplasty catheter.	LIT	NMM	Transluminal peripheral angioplasty catheter.
Unclassified ..	Ultrasonic surgical instrument	LFL	NLQ	Ultrasonic scalpel.
868.5150	Anesthesia conduction needle	BSP	NNH	Anesthetic conduction needle (with or without introducer).
868.5150	Anesthesia conduction needle	MIA	NMR	Short term spinal needle.
868.5730	Tracheal tube	BTR	NMA	Tracheal tube (with or without connector).
868.5905	Noncontinuous (IPPB)	BZD	NMC	Noncontinuous ventilator (respirator) mask.
870.1200	Diagnostic intravascular catheter	DQO	NLI	Angiography catheter.
870.1220	Electrode recording catheter	DRF	NLH	Electrode recording catheter.
870.1220	Electrode recording catheter	MTD	NLG	Intracardiac mapping catheter.
870.1230	Fiberoptic oximeter catheter	DQE	NMB	Fiberoptic oximeter catheter.
870.1280	Steerable catheter	DRA	NKS	Steerable catheter.
870.1290	Steerable catheter control system	DXX	NKR	Steerable catheter control system.
870.1330	Catheter guide wire	DQX	NKQ	Catheter guide wire.
870.1390	Trocar	DRC	NMK	Cardiovascular trocar.
870.1650	Angiographic injector and syringe	DXT	NKT	Angiographic injector and syringe.
870.1670	Syringe actuator for injector	DQF	NKW	Injector for actuator syringe.
870.2700	Oximeter	MUD	NMD	Tissue saturation oximeter.
870.2700	Oximeter	DQA	NLF	Oximeter.
870.3535	Intra-aortic balloon and control system.	DSP	NKO	Intra-aortic balloon and control system.
870.4450	Vascular clamp	DXC	NMF	Vascular clamp.
870.4885	External vein stripper	DWQ	NLJ	External vein stripper.
872.5470	Orthodontic plastic bracket	DYW	NLC	Orthodontic plastic bracket.
874.4680	Bronchoscope (flexible or rigid) and accessories.	BWH	NLE	Bronchoscope (nonrigid) biopsy forceps.
876.1075	Gastro-Urology biopsy instrument	FCG	NMX	G–U biopsy needle and needle set.
876.1075	Gastroenterology-urology biopsy instrument.	KNW	NLS	Biopsy instrument.
876.1500	Endoscope and accessories	FBK, FHP	NMY	Endoscopic needle.
876.1500	Endoscope and accessories	MPA	NKZ	Endoilluminator.
876.1500	Endoscope and accessories	GCJ	NLM	General and plastic surgery laparoscope.
876.1500	Endoscope and accessories	FHO	NLX	Spring-loaded Pneumoperitoneum Needle.
876.4300	Endoscopic electrosurgical unit and accessories.	FAS	NLW	Active urological electrosurgical electrode.
876.4300	Endoscopic unit accessories	FEH	NLV	Flexible suction coagulator electrode.
876.4300	Endoscopic electrosurgical unit and accessories.	KGE	NLU	Electric biopsy forceps.
876.4300	Endoscopic electrosurgical unit and accessories.	FDI	NLT	Flexible snare.
876.4300	Endoscopic electrosurgical unit and accessories.	KNS	NLR	Endoscopic (with or without accessories) Electrosurgical unit.
876.5010	Biliary catheter and accessories ..	FGE	NML	Biliary catheter.
876.5540	Blood access device and accessories.	LBW	NNF	Single needle dialysis set (co-axial flow).
876.5540	Blood access device and accessories.	FIE	NNE	Fistula needle.
876.5820	Hemodialysis systems and accessories.	FIF	NNG	Single needle dialysis set with and accessories uni-directional pump.
878.4300	Implantable clip	FZP	NMJ	Implantable clip.
878.4750	Implantable staple	GDW	NLL	Implantable staple.
880.5570	Hypodermic single lumen needle	FMI	NKK	Hypodermic single lumen needle.
880.5860	Piston syringe	FMF	NKN	Piston syringe.
882.4300	Manual cranial drills, burrs, trephines and accessories.	HBG	NLO	(Manual) drills, burrs, burrs, trephines and accessories.
882.4305	Powered compound cranial drills, burrs, trephines	HBF	NLP	(Powered, compound) drills, burrs, trephines and accessories.
882.4310	Powered simple cranial drills, burrs, trephines.	HBE	NLN	(Simple, powered) drills, burrs, trephines and accessories.
884.1720	Gynecologic laparoscope and accessories.	HET	NMH	Gynecologic laparoscope (and accessories).
884.6100	Assisted reproduction needle	MQE	NNB	Assisted reproduction needle.
886.4370	Keratome	HMY, HNO	NKY	Keratome blade.
886.4670	Phacofragmentation system	HQC	NKX	Phacoemulsification needle.

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE THE SUBMISSION OF VALIDATION DATA [1]—Continued

[Manufacturers who already have 510(k) clearance for these devices must submit validation data by January 26, 2004. Any new 510(k) will require validation data upon publication of this list.]

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for reprocessed device	Product code name for reprocessed device
892.5730	Radionuclide brachytherapy source.	IWF	NMP	Isotope needle.

[1] Hemodialyzers have been excluded from this list because the reuse of hemodialyzers is addressed in ''Guidance for Hemodialyzer Reuse Labeling'' (final draft issued on October 6, 1995).

III. Comments

You may submit written or electronic comments on these lists to the Dockets Management Branch (see **ADDRESSES**). You may submit a single copy of an electronic comment to *http://www.fda.gov/dockets/ecomments*. You should submit two copies of any mailed comments but individuals may submit one copy. You should identify your comment with the docket number found in brackets in the heading of this document. You may see any comments FDA receives in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk [1,2,3,3*]	Critical/semi-critical/non-critical	Premarket exempt
1	Cardio	Cardiopulmonary Bypass Marker ..	Unclassified		MAB	1	C	N
2	Cardio	Percutaneous & Operative Transluminal Coronary Angioplasty Catheter (PCTA).	post amendment	III	LOX	3	C	N
3	Cardio	Percutaneous Ablation Electrode ..	Post amendment	III	LPB	3	C	N
4	Cardio	Peripheral Transluminal Angioplasty (PTA) Catheter.	Unclassified		LIT	3	C	N
5	Cardio	Blood-Pressure Cuff	870.1120	II	DXQ	1	N	N
6	Cardio	Angiography Catheter	870.1200	II	DQO	3	C	N
7	Cardio	Electrode Recording Catheter	870.1220	II	DRF	3	C	N
8	Cardio	High-Density Array Catheter	870.1220	II	MTD	3	C	N
9	Cardio	Fiberoptic Oximeter Catheter	870.1230	II	DQE	3	C	N
10	Cardio	Steerable Catheter	870.1280	II	DRA	3	C	N
11	Cardio	Steerable Catheter Control System	870.1290	II	DXX	3	C	N
12	Cardio	Guide Wire	870.1330	II	DQX	3	C	N
13	Cardio	Angiographic Needle	870.1390	II	DRC	3	C	N
14	Cardio	Trocar	870.1390	II	DRC	3	C	N
15	Cardio	Syringes	870.1650	II	DXT	3	C	N
16	Cardio	Injector Type Syringe Actuator	870.1670	II	DQF	3	C	N
17	Cardio	Oximeter	870.2700	II	DQA	3	N	N
18	Cardio	Tissue Saturation Oximeter	870.2700	II	MUD	3	C	N
19	Cardio	Intra-Aortic Balloon System	870.3535	III	DSP	3	C	N
20	Cardio	Vascular Clamp	870.4450	II	DXC	3	C	N
21	Cardio	Device, Stabilizer, Heart	870.4500	I	MWS	2	C	Y
22	Cardio	External Vein Stripper	870.4885	II	DWQ	3	C	N
23	Cardio	Compressible Limb Sleeve	870.5800	II	JOW	1	N	N
24	Dental	Bur	872.3240	I	EJL	1	C	Y
25	Dental	Diamond Coated Bur	872.3240	I	EJL	3	C	Y
26	Dental	Diamond Instrument	872.4535	I	DZP	3	C	Y
27	Dental	AC-Powered Bone Saw	872.4120	II	DZH	2	C	N
28	Dental	Manual Bone Drill and Wire Driver	872.4120	II	DZJ	2	C	N
29	Dental	Powered Bone Drill	872.4120	II	DZI	2	C	N
30	Dental	Intraoral Drill	872.4130	I	DZA	1	C	Y
31	Dental	Injection Needle	872.4730	I	DZM	3	C	Y
32	Dental	Metal Orthodontic Bracket	872.5410	I	EJF	3	S	Y
33	Dental	Plastic Orthodontic Bracket	872.5470	II	DYW	3	S	N
34	ENT	Bur	874.4140	I	EQJ	1	C	Y
35	ENT	Diamond Coated Bur	874.4140	I	EQJ	3	C	Y
36	ENT	Microdebrider	874.4140	I	EQJ	3	C	Y
37	ENT	Microsurgical Argon Fiber Optic Laser Cable, For Uses Other Than Otology, Including Laryngology & General Use In Otolarngology.	874.4490	II	LMS	1	S	N
38	ENT	Microsurgical Argon Fiber Optic Laser Cable, For Use In Otology.	874.4490	II	LXR	1	S	N

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk [1,2,3,3*]	Critical/semi-critical/non-critical	Premarket exempt
39	ENT	Microsurgical Carbon-Dioxide Fiber Optic Laser Cable.	874.4500	II	EWG	1	S	N
40	ENT	Bronchoscope Biopsy Forceps (Non-Rigid).	874.4680	II	BWH	3	S	N
41	ENT	Bronchoscope Biopsy Forceps (Rigid).	874.4680	II	JEK	1	S	N
42	Gastro/Urology.	Biopsy Forceps Cover	876.1075	I	FFF	1	S	Y
43	Gastro/Urology.	Biopsy Instrument	876.1075	II	KNW	3	S	N
44	Gastro/Urology.	Biopsy Needle Set	876.1075	II	FCG	3	S	N
45	Gastro/Urology.	Biopsy Punch	876.1075	II	FCI	2	S	N
46	Gastro/Urology.	Mechanical Biopsy Instrument	876.1075	II	FCF	2	S	N
47	Gastro/Urology.	Non-Electric Biopsy Forceps	876.1075	I	FCL	3	S	Y
48	Gastro/Urology.	Cytology Brush For Endoscope	876.1500	II	FDX	2	S	N
49	Gastro/Urology.	Endoscope Accessories	876.1500	II	KOG	2	S	N
50	Gastro/Urology.	Extraction Balloons/Baskets	876.1500	II	KOG	2	S	N
51	Gastro/Urology.	Endoscopic Needle	876.1500	II	FBK	3	C	N
52	Gastro/Urology.	Simple Pneumoperitoneum Needle	876.1500	II	FHP	3	C	N
53	Gastro/Urology.	Spring Loaded Pneumoperitoneum Needle.	876.1500	II	FHO	3	C	N
54	Gastro/Urology.	Active Electrosurgical Electrode	876.4300	II	FAS	3	S	N
55	Gastro/Urology.	Biliary Sphincterotomes	876.5010, 876.1500	II	FGE	3	S	N
56	Gastro/Urology.	Electric Biopsy Forceps	876.4300	II	KGE	3	S	N
57	Gastro/Urology.	Electrosurgical Endoscopic Unit (With Or Without Accessories).	876.4300	II	KNS	3	S	N
58	Gastro/Urology.	Flexible Snare	876.4300	II	FDI	3	S	N
59	Gastro/Urology.	Flexible Suction Coagulator Electrode.	876.4300	II	FEH	3	S	N
60	Gastro/Urology.	Flexible Stone Dislodger	876.4680	II	FGO	3	S	Y
61	Gastro/Urology.	Metal Stone Dislodger	876.4680	II	FFL	3	S	Y
62	Gastro/Urology.	Needle Holder	876.4730	I	FHQ	1	C	Y
63	Gastro/Urology.	Non-Electrical Snare	876.4730	I	FGX	1	S	Y
64	Gastro/Urology.	Urological Catheter	876.5130	II	KOD	2	S	N
65	Gastro/Urology.	Single Needle Dialysis Set	876.5540	II	LBW, FIE	3	C	N
66	Gastro/Urology.	Hemodialysis Blood Circuit Accessories.	876.5820	II	KOC	2	S	N
67	Gastro/Urology.	Single Needle Dialysis Set	876.5820	II	FIF	3	C	N
68	GE/U	Hemorrhoidal Ligator	876.4400	II	FHN	2	C	N
69	General ..... Hospital	Implanted, Programmable Infusion Pump.	Post-amendment	III	LKK	3	C	N
70	General ..... Hospital	Needle Destruction Device	Post-amendment	III	MTV	1	N	N
71	General ..... Hospital	Non-Powered Flotation Therapy Mattress.	880.5150	I	IKY	2	N	Y
72	General ..... Hospital	Non AC-Powered Patient Lift	880.5510	I	FSA	2	N	Y
73	General ..... Hospital	Alternating Pressure Air Flotation Mattress.	880.5550	II	FNM	1	N	Y

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk [1,2,3,3*]	Critical/semi-critical/non-critical	Premarket exempt
74	General ..... Hospital	Temperature Regulated Water Mattress.	880.5560	I	FOH	2	N	Y
75	General ..... Hospital	Hypodermic Single Lumen Needle	880.5570	II	FMI	3	C	N
76	General ..... Hospital	Piston Syringe	880.5860	II	FMF	3	C	N
77	General ..... Hospital	Mattress Cover (Medical Purposes).	880.6190	I	FMW	2	N	Y
78	General ..... Hospital	Disposable Medical Scissors	880.6820	I	JOK	1	N	Y
79	General ..... Hospital	Irrigating Syringe	880.6960	I	KYZ, KYY	1	C	Y
80	Infection ..... Control	Surgical Gowns	878.4040	II	FYA	1	C	N
81	Lab	Blood Lancet	878.4800	I	FMK	1	C	Y
82	Neuro	Clip Forming/Cutting Instrument, ...	882.4190	I	HBS	3*	C	Y
83	Neuro	Drills, Burrs, Trephines & Accessories (Manual).	882.4300	II	HBG	3*	C	N
84	Neuro	Drills, Burrs, Trephines & Accessories (Compound, Powered).	882.4305	II	HBF	3*	C	N
85	Neuro	Drills, Burrs, Trephines & Accessories (Simple, Powered).	882.4310	II	HBE	3*	C	N
86	OB/GYN	Oocyte aspiration needle	Unclassified	II	MHK	3	C	N
87	OB/GYN	Laparoscope Accessories	884.1720	I	HET	2	C	Y
88	OB/GYN	Laparoscope Accessories	884.1720	II	HET	3	C	N
89	OB/GYN	Laparoscopic Dissectors	884.1720	I	HET	2	C	Y
90	OB/GYN	Laparoscopic Graspers	884.1720	I	HET	2	C	Y
91	OB/GYN	Laparoscopic Scissors	884.1720	I	HET	2	C	Y
92	OB/GYN	Insufflator Accessories (tubing, Verres needle, kits).	884.1730	II	HIF	3	C	Y
93	OB/GYN	Laparoscopic Insufflator	884.1730	II	HIF	2	N	N
94	OB/GYN	Endoscopic Electrocautery And Accessories.	884.4100	II	HIM	2	N	N
95	OB/GYN	Gynecologic Electrocautery (And Accessories).	884.4120	II	HGI	2	N	N
96	OB/GYN	Endoscopic Bipolar Coagulator-Cutter (And Accessories).	884.4150	II	HIN	2	N	N
97	OB/GYN	Culdoscopic Coagulator (And Accessories).	884.4160	II	HFI	2	N	N
98	OB/GYN	Endoscopic Unipolar Coagulator-Cutter (And Accessories).	884.4160	II	KNF	2	N	N
99	OB/GYN	Hysteroscopic Coagulator (And Accessories).	884.4160	II	HFH	2	N	N
100 ..	OB/GYN	Unipolar Laparoscopic Coagulator (And Accessories).	884.4160	II	HFG	2	N	N
101 ..	OB/GYN	Episiotomy Scissors	884.4520	I	HDK	1	C	Y
102 ..	OB/GYN	Umbilical Scissors	884.4520	I	HDJ	1	C	Y
103 ..	OB/GYN	Biopsy Forceps	884.4530	I	HFB	3	C	Y
104 ..	OB/GYN	Assisted reproduction needle	884.6100	II	MQE	3	C	N
105 ..	Ophthalmic ...	Endoilluminator	876.1500	II	MPA	3*	C	N
106 ..	Ophthalmic ...	Surgical Drapes	878.4370	II	KKX	2	C	N
107 ..	Ophthalmic ...	Ophthalmic Knife	886.4350	I	HNN	3	C	Y
108 ..	Ophthalmic ...	Keratome Blade	886.4370	I not exempt	HMY, HNO	3	C	N
109 ..	Ophthalmic ...	Phacoemulsification Needle	886.4670	II	HQC	3	C	N
110 ..	Ophthalmic ...	Phacoemulsification/ Phacofragmentation Fluidic.	886.4670	II	MUS	2	C	N
111 ..	Ophthalmic ...	Phacofragmentation Unit	886.4670	II	HQC	1	N	N
112 ..	Ortho	Saw Blades	878.4820	I	GFA, DWH, GEY, GET	1	C	Y
113 ..	Ortho	Surgical Drills	878.4820	I	GEY, GET	1	C	Y
114 ..	Ortho	Arthroscope accessories	888.1100	II	HRX	2	C	Y
115 ..	Ortho	Bone Tap	888.4540	I	HWX	1	C	Y
116 ..	Ortho	Burr	888.4540	I	HTT	1	C	Y
117 ..	Ortho	Carpal Tunnel Blade	888.4540	I	LXH	2	C	Y
118 ..	Ortho	Countersink	888.4540	I	HWW	1	C	Y
119 ..	Ortho	Drill Bit	888.4540	I	HTW	1	C	Y

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk [1,2,3,3*]	Critical/semi-critical/non-critical	Premarket exempt
120 ..	Ortho	Knife	888.4540	I	HTS	1	C	Y
121 ..	Ortho	Manual Surgical Instrument	888.4540	I	LXH	1	C	Y
122 ..	Ortho	Needle Holder	888.4540	I	HXK	1	C	Y
123 ..	Ortho	Reamer	888.4540	I	HTO	1	C	Y
124 ..	Ortho	Rongeur	888.4540	I	HTX	1	C	Y
125 ..	Ortho	Scissors	888.4540	I	HRR	1	C	Y
126 ..	Ortho	Staple Driver	888.4540	I	HXJ	1	C	Y
127 ..	Ortho	Trephine	888.4540	I	HWK	1	C	Y
128 ..	Ortho	Flexible Reamers/Drills	886.4070 878.4820	I	GEY, HRG	1	C	Y
129 ..	Ortho	External Fixation Frame	888.3040 888.3030	II	JEC KTW KTT	2	N	N
130 ..	Physical Medicine	Non-Heating Lamp for Adjunctive Use Inpatient Therapy.	Unclassified		NHN	1	N	N
131 ..	Physical Medicine	Electrode Cable, ...	890.1175	II	IKD	1	N	Y
132 ..	Physical Medicine	External Limb Component, Hip Joint.	890.3420	I	ISL	2	N	Y
133 ..	Physical Medicine	External Limb Component, Knee Joint.	890.3420	I	ISY	2	N	Y
134 ..	Physical Medicine	External Limb Component, Mechanical Wrist.	890.3420	I	ISZ	2	N	Y
135 ..	Physical Medicine	External Limb Component, Shoulder Joint.	890.3420	I	IQQ	2	N	Y
136 ..	Plastic Surgery	Stapler	878.4800	I	GAG, GEF, FHM, HBT	2	C	Y
137 ..	Radiology	Isotope Needle	892.5730	II	IWF	3	C	N
138 ..	Resp	Endotracheal Tube Changer	Unclassified	III	LNZ	3	C	N
139 ..	Resp	Anesthesia conduction needle	868.5150	II	BSP	3	C	N
140 ..	Resp	Short term spinal needle	868.5150	II	MIA	3	C	N
141 ..	Resp	Respiratory Therapy And Anesthesia Breathing Circuits.	868.5240	I	CAI	2	S	Y
142 ..	Resp	Oral And Nasal Catheters	868.5350	I	BZB	1	C	Y
143 ..	Resp	Gas Masks	868.5550	I	BSJ	1	S	Y
144 ..	Resp	Breathing Mouthpiece	868.5620	I	BYP	1	N	Y
145 ..	Resp	Tracheal Tube	868.5730	II	BTR	3	C	N
146 ..	Resp	Airway Connector	868.5810	I	BZA	2	S	Y
147 ..	Resp	CPAP Mask	868.5905	II	BZD	3	S	N
148 ..	Resp	Emergency Manual Resuscitator ..	868.5915	II	BTM	2	S	N
149 ..	Resp	Tracheobronchial Suction Catheter	868.6810	I	BSY	3	S	Y
150 ..	Surgery	AC-powered Orthopedic Instrument and accessories.	Unclassified		HWE	2	C	N
151 ..	Surgery	Breast Implant Mammary Sizer	Unclassified		MRD	1	C	N
152 ..	Surgery	Ultrasonic Surgical Instrument	Unclassified		LFL	3	C	N
153 ..	Surgery	Trocar	874.4420	I	KAB, KBG, KCI	3	C	Y
154 ..	Surgery	Endoscopic Blades	876.1500	II	GCP, GCR	2	C	N
155 ..	Surgery	Endoscopic Guidewires	876.1500	II	GCP, GCR	1	C	N
156 ..	Surgery	Inflatable External Extremity Splint	878.3900	I	FZF	1	N	Y
157 ..	Surgery	Noninflatable External Extremity Splint.	878.3910	I	FYH	1	N	Y
158 ..	Surgery	Catheter needle	878.4200	I	GCB	3	C	Y
159 ..	Surgery	Implantable Clip	878.4300	II	FZP	3	C	N
160 ..	Surgery	Electrosurgical And Coagulation Unit With Accessories.	878.4400	II	BWA	2	C	N
161 ..	Surgery	Electrosurgical Apparatus	878.4400	II	HAM	2	C	N
162 ..	Surgery	Electrosurgical Cutting & Coagulation Device & Accessories.	878.4400	II	GEI	2	C	N
163 ..	Surgery	Electrosurgical Device	878.4400	II	DWG	2	C	N
164 ..	Surgery	Electrosurgical Electrode	878.4400	II	JOS	2	C	N
165 ..	Surgery	Implantable Staple, Clamp, Clip for Suturing Apparatus.	878.4750	II	GDW	3	C	N
166 ..	Surgery	Percutaneous biopsy device	878.4800	I	MJG	3	C	Y
167 ..	Surgery	Gastro-Urology needle	878.4800	I	FHR	3	C	Y

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk [1,2,3,3*]	Critical/semi-critical/non-critical	Premarket exempt
168 ..	Surgery	Aspiration and injection needle	878.4800	I	GAA	3	C	Y
169 ..	Surgery	Biopsy Brush	878.4800	I	GEE	1	C	Y
170 ..	Surgery	Blood Lancet	878.4800	I	FMK	1	C	Y
171 ..	Surgery	Bone Hook	878.4800	I	KIK	1	C	Y
172 ..	Surgery	Cardiovascular Biopsy Needle	878.4800	I	DWO	3	C	Y
173 ..	Surgery	Clamp	878.4800	I	GDJ	1	C	Y
174 ..	Surgery	Clamp	878.4800	I	HXD	1	C	Y
175 ..	Surgery	Curette	878.4800	I	HTF	1	C	Y
176 ..	Surgery	Disposable Surgical Instrument	878.4800	I	KDC	1	C	Y
177 ..	Surgery	Disposable Vein Stripper	878.4800	I	GAJ	1	C	Y
178 ..	Surgery	Dissector	878.4800	I	GDI	1	C	Y
179 ..	Surgery	Forceps	878.4800	I	GEN	2	C	Y
180 ..	Surgery	Forceps	878.4800	I	HTD	2	C	Y
181 ..	Surgery	Gouge	878.4800	I	GDH	1	C	Y
182 ..	Surgery	Hemostatic Clip Applier	878.4800	I	HBT	2	C	Y
183 ..	Surgery	Hook	878.4800	I	GDG	1	C	Y
184 ..	Surgery	Manual Instrument	878.4800	I	MDM, MDW	1	C	Y
185 ..	Surgery	Manual Retractor	878.4800	I	GZW	1	C	Y
186 ..	Surgery	Manual Saw And Accessories	878.4800	I	GDR HAC	1	C	Y
187 ..	Surgery	Manual Saw And Accessories	878.4800	I	HAC	1	C	Y
188 ..	Surgery	Manual Surgical Chisel	878.4800	I	FZO	1	C	Y
189 ..	Surgery	Mastoid Chisel	878.4800	I	JYD	1	C	Y
190 ..	Surgery	Orthopedic Cutting Instrument	878.4800	I	HTZ	1	C	Y
191 ..	Surgery	Orthopedic Spatula	878.4800	I	HXR	1	C	Y
192 ..	Surgery	Osteotome	878.4800	I	HWM	1	C	Y
193 ..	Surgery	Rasp	878.4800	I	GAC	1	C	Y
194 ..	Surgery	Rasp	878.4800	I	HTR	1	C	Y
195 ..	Surgery	Retractor	878.4800	I	GAD	1	C	Y
196 ..	Surgery	Retractor	878.4800	I	HXM	1	C	Y
197 ..	Surgery	Saw	878.4800	I	HSO	1	C	Y
198 ..	Surgery	Scalpel Blade	878.4800	I	GES	1	C	Y
199 ..	Surgery	Scalpel Handle	878.4800	I	GDZ	1	C	Y
200 ..	Surgery	Scissors	878.4800	I	LRW	1	C	Y
201 ..	Surgery	Snare	878.4800	I	GAE	1	C	Y
202 ..	Surgery	Spatula	878.4800	I	GAF	1	C	Y
203 ..	Surgery	Staple Applier	878.4800	I	GEF	2	C	Y
204 ..	Surgery	Stapler	878.4800	I	GAG	2	C	Y
205 ..	Surgery	Stomach And Intestinal Suturing Apparatus.	878.4800	I	FHM	2	C	Y
206 ..	Surgery	Surgical Curette	878.4800	I	FZS	1	C	Y
207 ..	Surgery	Surgical Cutter	878.4800	I	FZT	1	C	Y
208 ..	Surgery	Surgical Knife	878.4800	I	EMF	1	S	Y
209 ..	Surgery	Laser Powered Instrument	878.4810	II	GEX	2	C	N
210 ..	Surgery	Ac-Powered Motor	878.4820	I	GEY	2	C	Y
211 ..	Surgery	Bit	878.4820	I	GFG	1	C	Y
212 ..	Surgery	Bur	878.4820	I	GFF, GEY	1	C	Y
213 ..	Surgery	Cardiovascular Surgical Saw Blade.	878.4820	I	DWH	1	C	Y
214 ..	Surgery	Chisel (Osteotome)	878.4820	I	KDG	1	C	Y
215 ..	Surgery	Dermatome	878.4820	I	GFD	1	C	Y
216 ..	Surgery	Electrically Powered Saw	878.4820	I	DWI	2	C	Y
217 ..	Surgery	Pneumatic Powered Motor	878.4820	I	GET	2	C	Y
218 ..	Surgery	Pneumatically Powered Saw	878.4820	I	KFK	2	C	Y
219 ..	Surgery	Powered Saw And Accessories	878.4820	I	HAB	2	C	Y
220 ..	Surgery	Saw Blade	878.4820	I	GFA	1	C	Y
221 ..	Surgery	Nonpneumatic Tourniquet	878.5900	I	GAX	1	N	Y
222 ..	Surgery	Pneumatic Tourniquet	878.5910	I	KCY	1	N	Y
223 ..	Surgery	Enodoscopic Staplers	888.4540	I	HXJ	2	C	Y
224 ..	Surgery	Trocar	876.1500 870.1390	II	GCJ, DRC	3	C	N
225 ..	Surgery	Surgical Cutting Accessories	878.4800, 874.4420	I	GDZ, GDX, GES, KBQ, KAS	2	C	Y
226 ..	Surgery	Electrosurgical Electrodes/Handles/Pencils.	876.4300 878.4400	II	HAM, GEI, FAS	2	C	N

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk [1,2,3,3*]	Critical/semi-critical/non-critical	Premarket exempt
227 ..	Surgery	Scissor Tips	878.4800, 884.4520, 874.4420	I	LRW, HDK, HDJ, JZB, KBD	2	C	Y
228 ..	Surgery	Laser Fiber Delivery Systems	878.4810 874.4500 886.4390 884.4550 886.4690	II	GEX EWG LLW HQF HHR HQB	1	C	N

1 = low risk according to RPS
2 = moderate risk according to RPS
3 = high risk according to RPS
3* = high risk due to neurological use

Dated: April 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Advisory Bulletin on Contractual Joint Ventures

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: The OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing certain contractual joint venture arrangements.

FOR FURTHER INFORMATION CONTACT: Vicki Robinson or Joel Schaer, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Special Advisory Bulletin: Contractual Joint Ventures (April 2003)

Introduction

This Special Advisory Bulletin addresses certain complex contractual arrangements for the provision of items and services previously identified as suspect in our 1989 Special Fraud Alert on Joint Venture Arrangements.[1] While much of the discussion in the 1989 Special Fraud Alert focused on investor referrals to newly formed entities, we observed that:

> [t]he Office of Inspector General has become aware of a proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays. Some examples of the items or services provided in these arrangements include clinical diagnostic laboratory services, durable medical equipment (DME), and other diagnostic services. Sometimes these deals are called ''joint ventures.'' *A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services,* or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services. (Emphasis added.)

Notwithstanding that caution, the Office of Inspector General (OIG) is concerned that contractual joint venture arrangements are proliferating.[2]

A. Questionable Contractual Arrangements

The federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act), prohibits knowingly and willfully soliciting, receiving, offering, or paying anything of value to induce referrals of items or services payable by a federal health care program. Kickbacks are harmful because they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal health care programs, and (4) result in unfair competition by freezing out competitors unwilling to pay kickbacks. Both parties to an impermissible kickback transaction may be liable. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. The OIG may also initiate administrative proceedings to exclude persons from the federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.

This Special Advisory Bulletin focuses on questionable contractual arrangements where a health care provider in one line of business (hereafter referred to as the ''Owner'') expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the ''Manager/Supplier'') to provide the new item or service to the Owner's existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals.

Some examples of potentially problematic contractual arrangements include the following:

[1] The 1989 Special Fraud Alert was reprinted in the **Federal Register** in 1994. *See* 59 FR 65372 (December 19, 1994). The Special Fraud Alert is also available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

[2] The kinds of contractual arrangements addressed in this Special Advisory Bulletin are sometimes referred to as ''joint ventures'' or ''contractual joint ventures'' or may be referenced by other terminology. For purposes of the analysis set forth in this Bulletin, a ''joint venture'' is any common enterprise with mutual economic benefit. The application of this Bulletin is not limited to ''joint ventures'' that meet technical qualifications under applicable state or common law.