(b) *Definition of ''Material''.* For purposes of this section, the term ''material'' means having a natural tendency to influence or be capable of influencing the decision to approve or deny the request to participate or enroll as a provider of services or supplier under a Federal health care program.

(c) *Sources.* The OIG's determination under paragraph (a) of this section will be made on the basis of information from the following sources:

(1) CMS;

(2) Medicaid State agencies;

(3) Fiscal agents or contractors or private insurance companies;

(4) Law enforcement agencies;

(5) State or local licensing or certification authorities;

(6) State or local professional societies; or

(7) Any other sources deemed appropriate by the OIG.

(d) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors:

(1) The nature and circumstances surrounding the false statement;

(2) Whether and to what extent payments were requested or received from the Federal health care program under the application, agreement, bid, or contract on which the false statement, omission, or misrepresentation was made; and

(3) Whether the individual or entity has a documented history of criminal, civil, or administrative wrongdoing.

[82 FR 4115, Jan. 12, 2017]

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) The OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986; and''

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges; and

(iv) Whether the physician has a documented history of criminal, civil, or administrative wrongdoing (the lack of any prior record is to be considered neutral).

(2) The period of exclusion may not exceed 5 years.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 82 FR 4116, Jan. 12, 2017]

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) *Circumstance for exclusion.* The OIG may exclude a physician whom it determines—

(1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled under Part B of the Medicare program (or his or her representative) for:

(i) Services of an assistant at surgery during a cataract operation, or

(ii) Charges that include a charge for an assistant at surgery during a cataract operation;

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality

Control Quality Improvement Organization (QIO) or Medicare carrier; and

(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;

(ii) The amount of the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(iv) Whether approval for the use of an assistant was requested from the QIO or carrier; and

(v) Whether the physician has a documented history of criminal, civil, or administrative wrongdoing (the lack of any prior record is to be considered neutral).

(2) The period of exclusion may not exceed 5 years.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998; 82 FR 4116, Jan. 12, 2017]

APPENDIX A TO SUBPART C OF PART 1001

The following is a sample written disclosure for purposes of satisfying the requirements of §1001.952(v)(3)(i)(B)(*1*)(*i*) of this part. This form is for illustrative purposes only; parties may, but are not required to, adapt this sample written disclosure form.

NOTICE OF AMBULANCE RESTOCKING PROGRAM

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X [or to a subpart of Hospital X, such as the emergency room] in the following category or categories: [insert description of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers]. [Optional: We only offer restocking of emergency transports.]

2. The restocking will include the following drugs and medical supplies, and linens, used for patient prior to delivery of the patient to Hospital X: [insert description of drugs and medical supplies, and linens to be restocked].

3. The ambulance providers [will/will not] be required to pay for the restocked drugs and medical supplies, and linens.

4. The restocked drugs and medical supplies, and linens, must be documented as follows: [insert description consistent with the documentation requirements described in §1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]

5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.

6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated:_____

/s/_____

Appropriate officer or official

[66 FR 62991, Dec. 4, 2001]

Subpart D—Waivers and Effect of Exclusion

§1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from the administrator of a Federal health care program (as defined in section 1128B(f) of the Act) that an exclusion from that program be waived with respect to an individual or entity, except that no