

the requested material upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request, except when the OIG or State Medicaid Fraud Control Unit (MFCU) reasonably believes that the requested material is about to be altered or destroyed, or

(ii) When the OIG or MFCU has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.

Reasonable request means a written request, signed by a designated representative of the OIG or MFCU and made by a properly identified agent of the OIG or an MFCU during reasonable business hours, where there is information to suggest that the person has violated statutory or regulatory requirements under Titles V, XI, XVIII, XIX, or XX of the Act. The request will include a statement of the authority for the request, the person's rights in responding to the request, the definition of "reasonable request" and "failure to grant immediate access" under part 1001, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion.* (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on Medicare or any of the State health care programs, beneficiaries or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

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

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, the length of the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 40753, July 30, 1993; 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999; 82 FR 4115, Jan. 12, 2017]

§ 1001.1401 Violations of PPS corrective action.

(a) *Circumstance for exclusion.* The OIG may exclude any hospital that CMS determines has failed substantially to comply with a corrective action plan required by CMS under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion.* The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on Medicare, Medicaid or any of the other Federal health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

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

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999]