Department of Health and Human Services

§ 60.12 Reporting adverse actions taken against clinical privileges.

(a) Reporting by health care entities to the NPDB. (1) Actions that must be reported and to whom the report must be made. Each health care entity must report to the NPDB and provide a copy of the report to the Board of Medical Examiners in the state in which the health care entity is located the following actions:

(i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days,

(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist.

(A) While the physician or dentist is under investigation by the health care

§ 60.11 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.

(a) What actions must be reported. Peer review organizations and private accreditation entities are required to report any negative actions or findings (as defined in §60.3 of this part) which are taken against a health care practitioner, health care entity, provider, or supplier to the NPDB and provide a copy to the appropriate state licensing or certification agency. The health care practitioner, health care entity, provider, or supplier must be licensed or otherwise authorized by the state to provide health care services. The actions taken must be as a result of formal proceedings (as defined in §60.3).

(b) What information must be reported. Each peer review organization and private accreditation entity must report the information as required in §60.9(b) of this part.

(c) What information may be reported, if known. Each peer review organization and private accreditation entity must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in this section as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

§ 60.12 Reporting adverse actions taken against clinical privileges.

(a) Reporting by health care entities to the NPDB. (1) Actions that must be reported and to whom the report must be made. Each health care entity must report to the NPDB and provide a copy of the report to the Board of Medical Examiners in the state in which the health care entity is located the following actions:

(i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days,

(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist.

(A) While the physician or dentist is under investigation by the health care
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entity relating to possible incompetence or improper professional conduct, or

(B) In return for not conducting such an investigation or proceeding, or

(iii) In the case of a health care entity which is a professional society, when it takes a professional review action concerning a physician or dentist.

(2) Voluntary reporting on other health care practitioners. A health care entity may report to the NPDB information as described in paragraph (a)(3) of this section concerning actions described in paragraph (a)(1) in this section with respect to other health care practitioners.

(3) What information must be reported. The health care entity must report the following information concerning actions described in paragraph (a)(1) of this section with respect to a physician or dentist:

(i) Name,
(ii) Work address,
(iii) Home address, if known,
(iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,
(v) Date of birth,
(vi) Name of each professional school attended and year of graduation,
(vii) For each professional license: the license number, the field of licensure, and the name of the state or territory in which the license is held,
(viii) DEA registration number, if known,
(ix) A description of the acts or omissions or other reasons for privilege loss, or, if known, for surrender,
(x) Action taken, date the action was taken, and effective date of the action, and
(xi) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(b) Reporting by the Board of Medical Examiners to the NPDB. Each Board must report any known instances of a health care entity’s failure to report information as required under paragraph (a)(1) of this section. In addition, each Board of Medical Examiners must simultaneously report this information to the appropriate state licensing board in the state in which the health care entity is located, if the Board of Medical Examiners is not such licensing board.

(c) Sanctions. (1) Health care entities. If the Secretary has reason to believe that a health care entity has substantially failed to report information in accordance with this section, the Secretary will conduct an investigation. If the investigation shows that the health care entity has not complied with this section, the Secretary will provide the entity with a written notice describing the noncompliance, giving the health care entity an opportunity to correct the noncompliance, and stating that the entity may request, within 30 days after receipt of such notice, a hearing with respect to the noncompliance. The request for a hearing must contain a statement of the material factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

(i) The request for a hearing is untimely,
(ii) The health care entity does not provide a statement of material factual issues in dispute, or
(iii) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the health care entity setting forth the reasons for denial. If a hearing is denied, or, if as a result of the hearing the entity is found to be in noncompliance, the Secretary will publish the name of the health care entity in the FEDERAL REGISTER. In such case, the immunity protections provided under section 411(a) of HCQIA will not apply to the health care entity for professional review activities that occur during the 3-year period beginning 30 days after the date of publication of the entity’s name in the FEDERAL REGISTER.

(2) Board of Medical Examiners. If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has
§ 60.13 Reporting Federal or state criminal convictions related to the delivery of a health care item or service.

(a) Who must report. Federal and state prosecutors must report criminal convictions against health care practitioners, providers, and suppliers related to the delivery of a health care item or service (regardless of whether the conviction is the subject of a pending appeal).

(b) What information must be reported. Entities described in paragraph (a) of this section must report the following information:

1. If the subject is an individual, personal identifiers, including:
   (i) Name,
   (ii) Social Security Number (or ITIN) (states must report this information, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974),
   (iii) Home address or address of record,
   (iv) Sex, and
   (v) Date of birth.

2. If the subject is an individual, that individual’s employment or professional identifiers, including:
   (i) Organization name and type,
   (ii) Occupation and specialty, if applicable, and
   (iii) National Provider Identifier (NPI).

3. If the subject is an organization, identifiers, including:
   (i) Name,
   (ii) Business address,
   (iii) Federal Employer Number (FEIN), or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),
   (iv) The NPI, and
   (v) Type of organization.

4. For all subjects:
   (i) A narrative description of the acts or omissions and injuries upon which the reported action was based,
   (ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,
   (iii) Name and location of court or judicial venue in which the action was taken,
   (iv) Docket or court file number,
   (v) Type of action taken,
   (vi) Statutory offense(s) and count(s),
   (vii) Name of primary prosecuting agency (or the plaintiff in civil actions),
   (viii) Date of sentence or judgment,
   (ix) Length of incarceration, detention, probation, community service, or suspended sentence,
   (x) Amounts of any monetary judgment, penalty, fine, assessment, or restitution,
   (xi) Other sentence, judgment, or orders,
   (xii) If the action is on appeal,
   (xiii) Name and address of the reporting entity, and
   (xiv) The name, title, and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) What information may be reported, if known. Entities described in paragraph (a) of this section and each state should report, if known, the following information:

1. If the subject is an individual, personal identifiers, including:
   (i) Other name(s) used,
   (ii) Other address(es), and
   (iii) FEIN, when used by the individual as a TIN.

2. If the subject is an individual, that individual’s employment or professional identifiers, including:
   (i) State professional license (including professional certification and registration) number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,
   (ii) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s);
   (iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and
   (iv) Nature of the subject’s relationship to each associated or affiliated health care entity.

3. If the subject is an organization, identifiers, including:
   (i) Other name(s) used,