

§ 155.206

45 CFR Subtitle A (10–1–20 Edition)

broker must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

(3) Inform individuals of the availability of the services described in paragraphs (c)(1) and (2) of this section and how to access such services.

(d) *Consumer assistance.* (1) The Exchange must have a consumer assistance function that meets the standards in paragraph (c) of this section, including the Navigator program described in §155.210. Any individual providing such consumer assistance must be trained regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the State, as implemented in the State, prior to providing such assistance or the outreach and education activities specified in paragraph (e) of this section.

(2) The Exchange must provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the Public Health Service Act, or any other appropriate State agency or agencies, for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage.

(e) *Outreach and education.* The Exchange must conduct outreach and education activities that meet the standards in paragraph (c) of this section to educate consumers about the Exchange and insurance affordability programs to encourage participation.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42859, July 17, 2013; 80 FR 10864, Feb. 27, 2015; 81 FR 12337, Mar. 8, 2016; 81 FR 94175, Dec. 22, 2016; 84 FR 17563, Apr. 25, 2019]

**§ 155.206 Civil money penalties for violations of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges.**

(a) *Enforcement actions.* If an individual or entity specified in paragraph (b) of this section engages in activity specified in paragraph (c) of this sec-

tion, the Department of Health and Human Services (HHS) may impose the following sanctions:

(1) Civil money penalties (CMPs), subject to the provisions of this section.

(2) Corrective action plans. In the notice of assessment of CMPs specified in paragraph (1) of this section, HHS may provide an individual or entity specified in paragraph (b) of this section the opportunity to enter into a corrective action plan to correct the violation instead of paying the CMP, based on evaluation of the factors set forth in paragraph (h) of this section. In the event that the individual or entity does not follow such a corrective action plan, HHS could require payment of the CMP.

(b) *Consumer assistance entities.* CMPs may be assessed under this section against the following consumer assistance entities:

(1) Individual Navigators and Navigator entities in a Federally-facilitated Exchange, including grantees, sub-grantees, and all personnel carrying out Navigator duties on behalf of a grantee or sub-grantee;

(2) Non-Navigator assistance personnel authorized under §155.205(d) and (e) and non-Navigator assistance personnel entities in a Federally-facilitated Exchange, including but not limited to individuals and entities under contract with HHS to facilitate consumer enrollment in QHPs in a Federally-facilitated Exchange; and

(3) Organizations that a Federally-facilitated Exchange has designated as certified application counselor organizations and individual certified application counselors carrying out certified application counselor duties in a Federally-facilitated Exchange.

(c) *Grounds for assessing CMPs.* HHS may assess CMPs against a consumer assistance entity if, based on the outcome of the investigative process outlined in paragraphs (d) through (i) of this section, HHS has reasonably determined that the consumer assistance entity has failed to comply with the Federal regulatory requirements applicable to the consumer assistance entity that have been implemented pursuant to section 1321(a)(1) of the Affordable Care Act, including provisions of

any agreements, contracts, and grant terms and conditions between HHS and the consumer assistance entity that interpret those Federal regulatory requirements or establish procedures for compliance with them, unless a CMP has been assessed for the same conduct under 45 CFR 155.285.

(d) *Basis for initiating an investigation of a potential violation*—(1) *Information*. Any information received or learned by HHS that indicates that a consumer assistance entity may have engaged or may be engaging in activity specified in paragraph (c) of this section may warrant an investigation. Information that might trigger an investigation includes, but is not limited to, the following:

(i) Complaints from the general public;

(ii) Reports from State regulatory agencies, and other Federal and State agencies; or

(iii) Any other information that indicates that a consumer assistance entity may have engaged or may be engaging in activity specified in paragraph (c) of this section.

(2) *Who may file a complaint*. Any entity or individual, or the legally authorized representative of an entity or individual, may file a complaint with HHS alleging that a consumer assistance entity has engaged or is engaging in an activity specified in paragraph (c) of this section.

(e) *Notice of investigation*. When HHS performs an investigation under this section, it must provide a written notice to the consumer assistance entity of its investigation. This notice must include the following:

(1) Description of the activity that is being investigated.

(2) Explanation that the consumer assistance entity has 30 days from the date of the notice to respond with additional information or documentation, including information or documentation to refute an alleged violation.

(3) State that a CMP might be assessed if the allegations are not, as determined by HHS, refuted within 30 days from the date of the notice.

(f) *Request for extension*. In circumstances in which a consumer assistance entity cannot prepare a response to HHS within the 30 days pro-

vided in the notice of investigation described in paragraph (e) of this section, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the consumer assistance entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or, if applicable, within an extended time frame, may result in HHS's imposition of a CMP depending upon the outcome of HHS's investigation of the alleged violation.

(g) *Responses to allegations of non-compliance*. In determining whether to impose a CMP, HHS may review and consider documents or information received or collected in accordance with paragraph (d)(1) of this section, as well as additional documents or information provided by the consumer assistance entity in response to receiving a notice of investigation in accordance with paragraph (e)(2) of this section. HHS may also conduct an independent investigation into the alleged violation, which may include site visits and interviews, if applicable, and may consider the results of this investigation in its determination.

(h) *Factors in determining noncompliance and amount of CMPs, if any*. In determining whether there has been non-compliance by the consumer assistance entity, and whether CMPs are appropriate:

(1) HHS must take into account the following:

(i) The consumer assistance entity's previous or ongoing record of compliance, including but not limited to compliance or noncompliance with any corrective action plan.

(ii) The gravity of the violation, which may be determined in part by—

(A) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread; and

(B) Whether the violation caused, or could reasonably be expected to cause, financial or other adverse impacts on consumer(s), and the magnitude of those impacts;

§ 155.206

45 CFR Subtitle A (10–1–20 Edition)

(2) HHS may take into account the following:

(i) The degree of culpability of the consumer assistance entity, including but not limited to—

(A) Whether the violation was beyond the direct control of the consumer assistance entity; and

(B) The extent to which the consumer assistance entity received compensation—legal or otherwise—for the services associated with the violation;

(ii) Aggravating or mitigating circumstances;

(iii) Whether other remedies or penalties have been assessed and/or imposed for the same conduct or occurrence; or

(iv) Other such factors as justice may require.

(i) *Maximum per-day penalty.* The maximum amount of penalty imposed for each violation is \$100 for each day for each consumer assistance entity for each individual directly affected by the consumer assistance entity's non-compliance; and where the number of individuals cannot be determined, HHS may reasonably estimate the number of individuals directly affected by the violation.

(j) *Settlement authority.* Nothing in §155.206 limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with paragraph (e) of this section or to compromise on any penalty provided for in this section.

(k) *Limitations on penalties—(1) Circumstances under which a CMP is not imposed.* HHS will not impose any CMP on:

(i) Any violation for the period of time during which none of the consumer assistance entities knew, or exercising reasonable diligence would have known, of the violation; or

(ii) The period of time after any of the consumer assistance entities knew, or exercising reasonable diligence would have known, of the failure, if the violation was due to reasonable cause and not due to willful neglect and the violation was corrected within 30 days of the first day that any of the consumer assistance entities against whom the penalty would be imposed knew, or exercising reasonable dili-

gence would have known, that the violation existed.

(2) *Burden of establishing knowledge.* The burden is on the consumer assistance entity or entities to establish to HHS's satisfaction that the consumer assistance entity did not know, or exercising reasonable diligence would have known, that the violation existed, as well as the period of time during which that limitation applies; or that the violation was due to reasonable cause and not due to willful neglect and was corrected pursuant to the elements in paragraph (k)(1)(ii) of this section.

(3) *Time limit for commencing action.* No action under this section will be entertained unless commenced, in accordance with §155.206(1), within six years from the date on which the violation occurred.

(1) *Notice of assessment of CMP.* If HHS proposes to assess a CMP in accordance with this section, HHS will send a written notice of this decision to the consumer assistance entity against whom the sanction is being imposed, which notice must include the following:

(1) A description of the basis for the determination;

(2) The basis for the CMP;

(3) The amount of the CMP, if applicable;

(4) The date the CMP, if applicable, is due;

(5) Whether HHS would permit the consumer assistance entity to enter into a corrective action plan in place of paying the CMP, and the terms of any such corrective action plan;

(6) An explanation of the consumer assistance entity's right to a hearing under paragraph (m) of this section; and

(7) Information about the process for filing a request for a hearing.

(m) *Appeal of proposed sanction.* Any consumer assistance entity against which HHS has assessed a sanction may appeal that penalty in accordance with the procedures set forth at 45 CFR part 150, subpart D.

(n) *Failure to request a hearing.* (1) If the consumer assistance entity does not request a hearing within 30 days of the issuance of the notice of assessment of CMP described in paragraph (1)

of this section, HHS may require payment of the proposed CMP.

(2) HHS will notify the consumer assistance entity in writing of any CMP that has been assessed and of the means by which the consumer assistance entity may pay the CMP.

(3) The consumer assistance entity has no right to appeal a CMP with respect to which it has not requested a hearing in accordance with paragraph (m) of this section unless the consumer assistance entity can show good cause in accordance with § 150.405(b) of this subchapter for failing to timely exercise its right to a hearing.

[79 FR 30342, May 27, 2014]

**§ 155.210 Navigator program standards.**

(a) *General requirements.* The Exchange must establish a Navigator program consistent with this section through which it awards grants to eligible public or private entities or individuals described in paragraph (c) of this section.

(b) *Standards.* The Exchange must develop and publicly disseminate—

(1) A set of standards, to be met by all entities and individuals to be awarded Navigator grants, designed to prevent, minimize and mitigate any conflicts of interest, financial or otherwise, that may exist for an entity or individuals to be awarded a Navigator grant and to ensure that all entities and individuals carrying out Navigator functions have appropriate integrity; and

(2) A set of training standards, to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure the entities and individuals are qualified to engage in Navigator activities, including training standards on the following topics:

(i) The needs of underserved and vulnerable populations;

(ii) Eligibility and enrollment rules and procedures;

(iii) The range of QHP options and insurance affordability programs; and

(iv) The privacy and security standards applicable under § 155.260.

(c) *Entities and individuals eligible to be a Navigator.* (1) To receive a Navigator

grant, an entity or individual must—

(i) Be capable of carrying out at least those duties described in paragraph (e) of this section;

(ii) Demonstrate to the Exchange that the entity has existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible for enrollment in a QHP;

(iii) Meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. Standards that would prevent the application of the provisions of title I of the Affordable Care Act include but are not limited to the following:

(A) Except as otherwise provided under § 155.705(d), requirements that Navigators refer consumers to other entities not required to provide fair, accurate, and impartial information.

(B) Except as otherwise provided under § 155.705(d), requirements that would prevent Navigators from providing services to all persons to whom they are required to provide assistance.

(C) Requirements that would prevent Navigators from providing advice regarding substantive benefits or comparative benefits of different health plans.

(D) Requiring that a Navigator hold an agent or broker license or imposing any requirement that, in effect, would require all Navigators in the Exchange to be licensed agents or brokers.

(E) Imposing standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to Navigator entities or individuals or applicable to the Exchange's implementation of the Navigator program.

(iv) Not have a conflict of interest during the term as Navigator; and,

(v) Comply with the privacy and security standards adopted by the Exchange as required in accordance with § 155.260.

(2) The Exchange must include an entity from at least one of the following