

§ 488.13 Loss of accreditation.

If an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the state survey agency will conduct a full review in a timely manner.

■ 17. Section 488.28 is amended by revising paragraph (a) to read as follows:

§ 488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient in one or more of the standards in the conditions of participation, conditions for coverage, or conditions for certification or requirements, it may participate in, or be covered under, the Medicare program only if the provider or supplier has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary. In the case of an immediate jeopardy situation, the Secretary may require a shorter time period for achieving compliance.

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PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 18. The authority citation for part 489 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 19. Section 489.1 is amended by revising paragraph (b) to read as follows:

§ 489.1 Statutory basis.

* * * * *

(b) Although section 1866 of the Act speaks only to providers and provider agreements, the following rules in this part also apply to the approval of supplier entities that, for participation in Medicare, are subject to a determination by CMS on the basis of a survey conducted by the state survey agency or CMS surveyors; or, in lieu of a state survey agency or CMS-conducted survey, accreditation by an accrediting organization whose program has CMS approval in accordance with § 488.4 at the time of the accreditation survey and accreditation decision, in accordance with the following:

(1) The effective date rules specified in § 489.13.

(2) The requirements specified in § 489.53(a)(2), (13), and (18), related to termination by CMS of participation in Medicare.

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■ 20. Section 489.3 is amended by revising the definition of “Immediate jeopardy” to read as follows:

§ 489.3 Definitions.

* * * * *

Immediate jeopardy means a situation in which the provider’s or supplier’s non-compliance with one or more requirements, conditions of participation, conditions for coverage, or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

■ 21. Section 489.53 is amended by—

■ A. Revising paragraphs (a) introductory text, (a)(2), (a)(13).

■ B. Adding reserved paragraph (a)(17).

■ C. Adding paragraph (a)(18).

■ D. Revising paragraph (d)(2)(i) introductory text.

The additions and revisions read as follows:

§ 489.53 Termination by CMS.

(a) Basis for termination of agreement. CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider, and may, in addition to the applicable requirements in this chapter governing the termination of agreements with suppliers, terminate the agreement with any supplier to which the failings in paragraphs (a)(2), (a)(13), and (a)(18) of this section are attributable:

* * * * *

(2) The provider or supplier places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

* * * * *

(13) The provider or supplier refuses to permit photocopying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements.

* * * * *

(17) [Reserved]

(18) The provider or supplier fails to grant immediate access upon a reasonable request to a state survey agency or other authorized entity for the purpose of determining, in accordance with § 488.3, whether the provider or supplier meets the applicable requirements, conditions of participation, conditions for coverage or conditions for certification.

* * * * *

(d) * * *

(2) * * *

(i) Hospitals. If CMS finds that a hospital is in violation of § 489.24 (a) through (f), and CMS determines that

the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, CMS—

* * * * *

CMS–3255–P

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 15, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 13, 2013.

Kathleen Sebelius,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 155

[CMS–9955–P]

RIN 0938–AR75

Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The proposed regulations would create conflict-of-interest, training and certification, and meaningful access standards applicable to Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and to non-Navigator assistance personnel in State-based Exchanges that are funded through federal Exchange Establishment grants. These proposed standards would help ensure that Navigators and non-Navigator assistance personnel will be fair and impartial and will be appropriately trained, and that they will provide services and information in a manner that is accessible.

The proposed regulations would also make two amendments to the existing regulation for Navigators that would apply to all Navigators in all Affordable Insurance Exchanges (Exchanges), including State-based Exchanges, clarifying that any Navigator licensing, certification, or other standards

prescribed by the state or Exchange must not prevent the application of the provisions of title I of the Affordable Care Act; and adding to the list of entities ineligible to become Navigators, those entities with relationships to issuers of stop loss insurance, including those who are compensated directly or indirectly by issuers of stop loss insurance in connection with enrollment in Qualified Health Plans or non-Qualified Health Plans. The proposed regulations would also clarify that the same ineligibility criteria that apply to Navigators would also apply to non-Navigator assistance personnel providing services in any Federally-facilitated Exchanges, including in State Consumer Partnership Exchanges, and to federally funded non-Navigator assistance personnel in State-based Exchanges.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 6, 2013.

ADDRESSES: In commenting, please refer to file code CMS-9955-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9955-P, P.O. Box 8010, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9955-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Joan Matlack, (888) 393-2789.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (800) 743-3951.

I. Background

A. Introduction

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111-152) was enacted on March 30, 2010. These laws are collectively known as the Affordable Care Act.

Beginning on October 1, 2013, individuals and small businesses will be able to purchase private health insurance through state-based competitive marketplaces called Affordable Insurance Exchanges (Exchanges), also known as the Health Insurance Marketplaces.

The Exchanges will provide competitive marketplaces where individuals and small employers can compare available private health insurance options on the basis of price, quality, and other factors. The Exchanges, which will offer coverage that is effective beginning on January 1, 2014, will help enhance competition in the health insurance market, improve choice of affordable health insurance, and give small businesses the same purchasing power as large businesses.

Pursuant to sections 1311(b) and 1321(b) of the Affordable Care Act, each state has the opportunity to establish an Exchange that—(1) Facilitates the purchase of insurance coverage by qualified individuals through Qualified Health Plans (QHPs); (2) assists qualified employers in the enrollment of their employees in QHPs; and (3) meets other standards specified in the Affordable Care Act. These are referred to as State-Based Exchanges.

Section 1321(c)(1) of the Affordable Care Act requires the Secretary of HHS ("Secretary") to establish and operate Exchanges within states that either: (1) do not elect to establish an Exchange, or (2) as determined by the Secretary on or before January 1, 2013, will not have an Exchange operational by January 1, 2014. These HHS-operated Exchanges are referred to as Federally-facilitated Exchanges. The Secretary has also explained through sub-regulatory guidance that these Federally-facilitated Exchanges may include State Partnership Exchanges in which states may assume significant responsibility for key Exchange functions.¹ Generally, a State Partnership Exchange will take one of two forms: a State Plan Management Partnership Exchange, or a State Consumer Partnership Exchange (Consumer Partnership Exchange).

Consumers can receive assistance from a variety of sources when seeking access to health insurance coverage through an Exchange. Sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act, and the regulation implementing those provisions, 45 CFR

¹ See 77 FR 18310, 18325-26 (Mar. 27, 2012); General Guidance on Federally-facilitated Exchanges (May 16, 2012) at <http://cciio.cms.gov/resources/files/ffe-guidance-05-16-2012.pdf>; and Guidance on the State Partnership Exchange (Jan. 3, 2013) at <http://cciio.cms.gov/resources/files/partnership-guidance-01-03-2013.pdf>.

155.210, direct all Exchanges to award grants to Navigators that will provide fair and impartial information to consumers about health insurance, the Exchange, QHPs, and insurance affordability programs including premium tax credits, Medicaid and the Children's Health Insurance Program (CHIP); and that will provide referrals to consumer assistance programs (CAP) and health insurance ombudsmen for enrollees with grievances, complaints, or questions about their health plan or coverage. Navigators are an important resource for all consumers, particularly communities that are under-served by and under-represented in the current health insurance market. Navigators will not make eligibility determinations and will not select QHPs for consumers or enroll applicants into QHPs, but will help consumers through the eligibility and enrollment process. The Exchange regulations, at 45 CFR 155.400(a), state that "[t]he Exchange must accept a QHP selection from an applicant * * * and must—(1) Notify the issuer of the applicant's selected QHP; and (2) Transmit information necessary to enable the QHP issuer to enroll the applicant" (emphasis added). Additionally, as articulated in 45 CFR § 155.310(d), the Exchange is responsible for making eligibility determinations. Taken together, these regulations clearly mean that the Exchange, not Navigators, must determine eligibility and enroll applicants into QHPs. Additionally, a Navigator cannot make the decision for an applicant as to which QHP to select. That said, Navigators may play an important role in facilitating a consumer's enrollment in a QHP by providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application, clarifying the distinctions among QHPs, and helping qualified individuals make informed decisions during the health plan selection process.

The Exchange regulations also authorize Exchanges to perform certain consumer service functions in addition to the Navigator program. Federal regulations at 45 CFR § 155.205(d) and (e) provide that each Exchange must conduct consumer assistance activities as well as outreach and education activities to educate consumers about the Exchange and insurance affordability programs to encourage participation. The activities under § 155.205(d) and (e) include, but are not limited to, the Navigator grant program. Establishing a non-Navigator consumer assistance program pursuant to § 155.205(d) and (e) will help ensure

that the Exchange is providing outreach, education, and assistance to as broad a range of consumers as possible so that all consumers can receive help when accessing health insurance coverage through an Exchange.

A program established to fulfill the consumer assistance, education, and outreach functions under § 155.205(d) and (e) through in-person consumer support, other than a Navigator program, is referred to in the proposed regulation and in this preamble as a "non-Navigator assistance program authorized by § 155.205(d) and (e)" or more simply as a "non-Navigator assistance program." In addition, we refer to persons carrying out these consumer assistance, education, and outreach functions under § 155.205(d) and (e) as "non-Navigator assistance personnel carrying out consumer assistance functions under § 155.205 (d) and (e)" or "non-Navigator entities or individuals authorized to carry out consumer assistance functions under § 155.205 (d) and (e)" or more simply as "non-Navigator assistance personnel." Non-Navigator assistance programs include what have sometimes been referred to as "in-person assistance programs." Similarly, non-Navigator assistance personnel include what have sometimes been referred to as "in-person assistance personnel." Therefore, when references are made in this preamble or in the proposed regulation to non-Navigator assistance programs or non-Navigator assistance personnel, those references also apply to in-person assistance programs or in-person assistance personnel, respectively.

State-based Exchanges may, but need not, establish non-Navigator assistance programs to provide consumer assistance, education, and outreach under § 155.205(d) and (e). Additionally, as a condition of a state's participation in a Consumer Partnership Exchange, the state will establish and operate a non-Navigator assistance program in a way that is consistent with the policies and interpretations HHS adopts for § 155.205(d) and (e) for the Federally-facilitated Exchanges. This does not affect the obligation of a Consumer Partnership Exchange to establish and operate a Navigator program, however. HHS will have responsibility for the inherently governmental function of awarding federal Navigator grants for the Federally-facilitated Exchanges, including State Partnership Exchanges. Federally-facilitated Exchanges, other than Consumer Partnership Exchanges, do not anticipate including a non-Navigator assistance program.

Section 1311(i)(6) prohibits Exchanges from using section 1311(a) grant funds to fund Navigator grants. However, section 1311(a) grant funds may be used to cover the Exchange's cost of administering the Navigator program, including, for example, the cost of Navigator training, grants management, and oversight.

State-based Exchanges and state partners in Consumer Partnership Exchanges may use section 1311(a) Exchange Establishment grants to fund non-Navigator assistance programs consistent with the following discussion.

Together, section 1311(a)(4)(B) and section 1311(d)(5)(A) provide that, as long as grant funds under section 1311(a) are available to the state, a State-based Exchange need not be self-sustaining during its initial year of operation. Accordingly, as long as section 1311(a) grant funds are available to the state, a State-based Exchange may not have sufficient funds independent of section 1311(a) grant funds during its initial year of operation to achieve all of the goals of the Navigator program. As a transitional policy in such circumstances, a State-based Exchange may use a non-Navigator assistance program in its initial year of operation to fill in any gaps in its Navigator program and otherwise ensure that the full range of services that its Navigator program will provide in subsequent years are provided during its initial year of operation. As the State-based Exchange becomes self-sustaining, the roles of the non-Navigator assistance program and the Navigator program may change. We note that, after the State-based Exchange becomes self-sustaining, the State-based Exchange can choose to establish or continue a non-Navigator assistance program, as a supplement to its fully-funded Navigator program. Similarly, a State-based Exchange that is self-sustaining from the outset, because section 1311(a) grant funds are no longer available to the state, can make a similar choice. In both such circumstances, the non-Navigator assistance program would have to be funded through some source other than section 1311(a) grant funds.

Section 1311(a) grant funds are available for non-Navigator assistance programs in Consumer Partnership Exchanges because the state has elected to establish and operate outreach, educational, and assistance activities to assist in its transition to a State-based Exchange, as a condition of its participation in the Consumer Partnership Exchange. Such activities do not purport to, nor do they in fact, supplant the obligation of the federal

government to establish a Navigator program. When a state partner in a Consumer Partnership Exchange transitions to a State-Based Exchange, the discussion of State-Based Exchanges above will apply.

While section 1311(i)(1) directs that the Navigator program be a grant program, State-based Exchanges and state partners in a Consumer Partnership Exchange have the flexibility to build a non-Navigator assistance program through contracts, direct hiring, or grants, subject to state law. Utilizing funding mechanisms other than grants for non-Navigator assistance programs may be particularly important to ensure that State-based Exchanges have enhanced flexibility to utilize non-Navigator assistance personnel to fill in any gaps in their Navigator programs or to appropriately supplement their Navigator program, as described above, by, for example, serving communities that may not be reached by their Navigator program.

B. Legislative and Regulatory Overview

Section 1311 of the Affordable Care Act generally establishes the creation of Exchanges and outlines various requirements and standards Exchanges must satisfy. Specifically, pursuant to sections 1311(b) and 1321(b) of the Affordable Care Act, each state has the opportunity to establish an Exchange.

Sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act direct each Exchange to establish a program under which it awards grants to Navigators who will carry out a list of required duties. A final rule implementing sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act was published on March 27, 2012 (77 FR 18310), and is codified at 45 CFR § 155.210.

Section 1311(i)(3) of the Affordable Care Act lists the duties Navigators must perform. Section 155.210(e) interprets these duties to include: maintaining expertise in eligibility, enrollment, and program specifications; conducting public education activities to raise awareness about the Exchange; providing information and services in a fair, accurate, and impartial manner, including information that acknowledges other health programs such as Medicaid and CHIP; facilitating selection of a QHP; providing referrals for consumers with questions, complaints, or grievances to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the Public Health Service Act (PHS Act), or any other appropriate state agency or agencies; providing information in a culturally and

linguistically appropriate manner, including to persons with limited English proficiency; and ensuring accessibility and usability of Navigator tools and functions for persons with disabilities.

Section 1311(i)(4) directs the Secretary to establish standards for Navigators, including provisions to ensure that any entity selected as a Navigator is qualified, and licensed if appropriate, to engage in the Navigator activities required by the law and to avoid conflicts of interest. 45 CFR 155.210(b)(1), which interprets this provision, directs each Exchange to “develop and publicly disseminate * * * [a] set of standards, to be met by all entities and individuals 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.” Additionally, 45 CFR 155.210(c)(1)(iv) provides that a Navigator must not have a conflict of interest during its term as Navigator. 45 CFR 155.210(b)(2) directs Exchanges to develop and disseminate a set of training standards, to be met by all entities and individuals carrying out Navigator functions, to ensure Navigator expertise in the needs of underserved and vulnerable populations; eligibility and enrollment rules and procedures; the range of QHP options and insurance affordability programs; and privacy and security requirements applicable to personally identifiable information. This proposal develops and disseminates standards under § 155.210(b)(1) and (2) for the Federally-facilitated Exchanges, including State Partnership Exchanges, and for non-Navigator assistance personnel in State-based Exchanges that are funded through federal Exchange Establishment grants. These standards could also be used by State-based Exchanges at their discretion for their Navigator programs and for any non-Navigator assistance programs not funded with 1311(a) Exchange Establishment grants.

45 CFR 155.210(c)(1)(iii) also interprets section 1311(i)(4), and directs that entities or individuals must meet any licensing, certification, or other standards prescribed by the state or Exchange, if applicable, in order to receive a Navigator grant.

Section 1311(i)(4) of the Affordable Care Act also specifies that under the standards established by the Secretary, Navigators shall not be health insurance issuers or receive any consideration directly or indirectly from any health

insurance issuer in connection with the enrollment of any qualified individuals or employees of a qualified employer in QHPs. 45 CFR § 155.210(d), which interprets this provision, prohibits Navigators from being health insurance issuers. It also provides that Navigators should not receive any compensation directly or indirectly from health insurance issuers in connection with the enrollment of qualified individuals or employees of a qualified employer, whether that enrollment is in QHPs or in non-QHPs. Section 155.210(d) further clarifies that a Navigator must not be a subsidiary of a health insurance issuer or be an association that includes members of, or lobbies on behalf of, the insurance industry.

Section 1311(i)(5) of the Affordable Care Act directs the Secretary to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial.

Provisions of the Exchange regulations, at 45 CFR 155.210(c)(2), direct the Exchange to select at least two different types of entities as Navigators, one of which must be a community and consumer-focused non-profit group.

Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory standards related to Exchanges, QHPs, and other components of title I of the Affordable Care Act.

Section 1321(c)(1) of the Affordable Care Act requires the Secretary to establish and operate Exchanges within states that either: (1) do not elect to establish an Exchange, or (2) as determined by the Secretary on or before January 1, 2013, will not have an Exchange operational by January 1, 2014. These HHS-operated Exchanges are referred to as Federally-facilitated Exchanges, and include State Partnership Exchanges.

Section 1321(d) of the Affordable Care Act states that nothing in title I of that Act shall be construed to preempt any state law that does not prevent the application of the provisions of the title. Title I of the Affordable Care Act includes all provisions related to Exchanges, including the Navigator provisions.

Provisions of the Exchange regulations, at 45 CFR 155.205(d), direct Exchanges to have a consumer assistance function that meets the accessibility standards set forth in § 155.205(c). This consumer assistance function includes the Navigator program at section 1311(i) of the Affordable Care Act and 45 CFR 155.210, but is not limited to the Navigator program.

45 CFR 155.205(e) directs Exchanges to conduct outreach and education activities that also meet the accessibility standards in § 155.205(c), and to educate consumers about the Exchange and insurance affordability programs to encourage participation. The accessibility standards for § 155.205(d) and (e), as detailed in § 155.205(c), include a requirement that applicants and enrollees be provided information in plain language and in a manner that is accessible and timely for persons with disabilities and individuals with limited English proficiency. Additionally, a notice of proposed rulemaking published on January 22, 2013 would amend § 155.205(d)² to require any individual providing consumer assistance under § 155.205(d) to 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 consumer assistance. Once finalized, that rule will apply to and require such training for non-Navigator assistance personnel.

HHS has also published a proposed a rule (78 FR 4594) that would create a new section 45 CFR § 155.225, proposing to require each Exchange to certify staff and volunteers of Exchange-designated organizations and organizations designated by State Medicaid and Children's Health Insurance Program agencies to serve as certified application counselors in the Exchange.

C. Overview of Proposed Rule

First, this proposed regulation would amend § 155.210(c)(1)(iii) to clarify that any Navigator licensing, certification, or other standards prescribed by the state or Exchange must not prevent the application of the provisions of title I of the Affordable Care Act. The proposed rule would also amend § 155.210(d) to clarify that a Navigator cannot be an issuer of, or a subsidiary of an issuer of, stop loss insurance, and cannot receive any consideration, directly or indirectly, from an issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP. These proposed amendments to § 155.210 would be applicable to Navigators in all Exchanges, including

Federally-facilitated Exchanges, State Partnership Exchanges, and State-based Exchanges.

Second, this proposed rule would add a new provision at 45 CFR 155.215 that would establish conflict-of-interest, training, and accessibility standards applicable to Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges. We also propose that these standards would apply to non-Navigator assistance programs and personnel in State-based Exchanges that are funded through federal section 1311(a) Exchange Establishment grants.

Proposed section 155.215(a) provides details on the set of conflict-of-interest standards applicable to these Navigators and non-Navigator personnel. Proposed § 155.215(a)(2)(i) would also establish that the non-Navigator assistance personnel described above must comply with the same set of conflict-of-interest prohibitions that apply to Navigators under § 155.210(d). Section 155.215(b) proposes standards related to training, certification, and recertification for these Navigators and non-Navigator personnel. These standards include details about the requirement to be certified, to register and receive training, the content required for training, and the requirement to receive a passing score on all HHS-approved certification examinations after training. Proposed § 155.215(c) and (d) would establish standards for these Navigators and non-Navigator personnel to ensure meaningful access to their services by individuals with limited English proficiency and people with disabilities. The standards proposed at 155.215(c) and (d) should be read together with all other applicable standards issued by the Secretary related to ensuring meaningful access by individuals with limited English proficiency and people with disabilities.

State-based Exchanges would not be required to use the standards proposed in § 155.215 for their Navigators, or for non-Navigator assistance programs not funded through section 1311(a) Exchange Establishment grants. However, we believe that State-based Exchanges may find the federal standards to be useful models, and could draw upon them as they develop and disseminate conflict-of-interest and training standards for Navigators pursuant to § 155.210(b), or when establishing standards for any non-Navigator assistance program that is established by the State-based Exchange that is not funded by federal 1311(a) Exchange Establishment grants.

In addition, while the conflict-of-interest, training and meaningful access standards that are now being proposed would apply to the Navigators and non-Navigator assistance personnel described above, we have not proposed that the standards would also apply to certified application counselors. Certified application counselors have been proposed as an additional source of consumer assistance, required in every Exchange, in a separate proposed rule (78 FR 4594), but that rule has not yet been finalized. We are, however, requesting public comments regarding whether all or some of the standards being proposed for Navigators and non-Navigator assistance personnel in this proposed regulation should also apply to certified application counselors in the event that every Exchange is required to establish a certified application counselor program after publication of a final rule.

II. Provisions of the Proposed Rule

A. Navigator Program Standards (Proposed Amendments to § 155.210)

The proposed rule contains two amendments to specific provisions of the existing Navigator regulation, § 155.210. These proposed amendments would apply to Navigators in all Exchanges, including Federally-facilitated Exchanges, State Partnership Exchanges and State-based Exchanges.

1. Entities and Individuals Eligible to be a Navigator (Proposed Amendment to § 155.210(c)(1)(iii))

Section 155.210(c)(1)(iii), implementing section 1311(i)(4) of the Affordable Care Act, currently directs that, to receive a Navigator grant, an entity or individual must "meet any licensing, certification or other standards prescribed by the state or Exchange, if applicable." Section 1321(d) of the Affordable Care Act provides that state laws that do not prevent the application of the provisions of title I of the Affordable Care Act are not preempted.

The proposed rule would clarify that any Navigator licensing, certification, or other standards prescribed by the state or Exchange should not prevent the application of the provisions of title I of the Affordable Care Act. Thus, for example, as HHS has previously advised (see 77 FR 18310 at 18331–32), a requirement by a state or an Exchange that Navigators be agents and brokers or obtain errors and omissions coverage would violate the requirement at § 155.210(c)(2) that at least two types of entities must serve as Navigators, because it would mean that only agents

² See Notice of Proposed Rulemaking on Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 FR 4594, 4710 (Jan. 22, 2013).

or brokers could be Navigators. In addition, holding an agent or broker license is neither necessary, nor by itself sufficient, to perform the duties of a Navigator, as these licenses generally do not address areas in which Navigators need expertise, including the public coverage options that would be available to some consumers. Similarly, if a State or Exchange required all Navigators to hold a producer license, or if a producer license was required to carry out any of the required Navigator duties, this would also conflict with § 155.210(c)(2), because in that event, all Navigators in the Exchange would be licensed agents or brokers, as defined in § 155.20.

Therefore, we propose to amend § 155.210(c)(1)(iii) to clarify, consistent with Affordable Care Act section 1321(d), that to receive a Navigator grant, an entity or individual must meet any licensing, certification or other standard prescribed by the State or Exchange, if applicable, as long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. We solicit public comments on this proposed amendment.

2. Prohibition on Navigator Conduct (Proposed Amendment to § 155.210(d))

Under § 155.210(d), a Navigator may not be a health insurance issuer; be a subsidiary of a health insurance issuer; be an association that includes members of, or lobbies on behalf of, the insurance industry; or receive any consideration, directly or indirectly, from any health insurance issuer in connection with the enrollment of any individuals or employees in a QHP or non-QHP. We propose to amend section 155.210(d) to further clarify that a Navigator must also not be an issuer of stop loss insurance, or a subsidiary of an issuer of stop loss insurance, and must not receive any consideration, directly or indirectly, from any issuer of stop loss insurance in connection with the enrollment of individuals or employers in a QHP or non-QHP.³

Section 1311(i)(3)(B) of the Affordable Care Act directs that a Navigator must distribute fair and impartial information concerning enrollment in QHPs. Section 1311(i)(5) of the Affordable Care Act further directs that the Secretary shall

establish standards to ensure that information made available by Navigators is fair, accurate, and impartial. In addition, section 1311(i)(4) directs the Secretary to establish standards to avoid conflicts of interest by Navigators. Existing regulations at 45 CFR 155.210(c)(1)(iv) and (e)(2) also direct that Navigators must not have a conflict of interest during their term as a Navigator, and must provide information and services in a fair, accurate, and impartial manner. Taken together, these requirements indicate that a Navigator should not have a conflict of interest when presenting information or providing the range of coverage choices to individuals or small employers who receive the Navigator's assistance. Similarly, the Navigator must not have a personal interest in the coverage choices made by individuals or employers who receive the Navigator's assistance. More specifically, with respect to the assistance offered by a Navigator to a small employer, a Navigator should not have a personal interest in whether a small employer chooses to self-insure its employees, or chooses to enroll in fully-insured coverage inside or outside the Exchange.

We believe that an issuer of stop loss insurance, a subsidiary of an issuer of stop loss insurance, or an individual or entity receiving consideration from any issuer of stop loss insurance in connection with enrollment in a QHP or non-QHP, would have conflicts of interest prohibited by § 155.210(c)(1)(iv) and such conflicts of interest would compromise the ability of a Navigator to provide information and services in a fair, accurate, and impartial manner as required by § 155.210(e)(2).

Navigators with a financial relationship with an issuer of stop loss insurance raise the same kinds of concerns that would be present for a Navigator with a relationship with a health insurance issuer (or an entity receiving consideration from a health insurance issuer). Such Navigators could have a financial incentive to encourage small employers towards self-funding and might not present all coverage options, including insured options, to small employers in a fair, accurate, and impartial manner. In addition, such conflicts of interest might interfere with a Navigator's duty to "facilitate selection of a QHP," as required by § 155.210(e)(3).

The proposed amendments would help ensure that Navigators provide any small employers that request help from a Navigator with information and services in a fair, accurate, and impartial manner, and that such information facilitate small employers' selection of

QHPs in Small Business Health Options (SHOP) Exchanges, if they choose to enroll in such coverage. We solicit public comments on this proposal.

B. Standards Applicable to Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 in a Federally-Facilitated Exchange and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (Proposed § 155.215)

1. Conflict-of-Interest Standards (Proposed § 155.215(a))

The proposed regulation proposes conflict-of-interest standards that are substantially similar for both Navigators and non-Navigator assistance personnel. These proposed conflict-of-interest standards would apply to all Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange (including a State Partnership Exchange), and to federally-funded non-Navigator assistance personnel in a State-based Exchange.

The standards applicable to Navigators interpret the requirements at section 1311(i)(4) of the Affordable Care Act and 45 CFR 155.210(c)(1)(iv) and (d). In addition, these standards would help ensure that Navigators provide information in a fair, accurate, and impartial manner, pursuant to Affordable Care Act section 1311(i)(5) and 45 CFR 155.210(e)(2). These standards also follow from 45 CFR 155.210(b), which specifies that Exchanges establish a set of conflict-of-interest standards applicable to Navigators in the Exchange.

We also believe that non-Navigator assistance personnel who carry out consumer outreach, assistance, and education in Federally-facilitated Exchanges, including State Partnership Exchanges, and non-Navigator assistance personnel in State-based Exchanges that are funded through Exchange Establishment grants should be subject to conflict-of-interest standards. To be helpful to the public, we believe that services provided under § 155.205(d) and (e) should be carried out in a fair, impartial, and unbiased manner. Applying conflict-of-interest standards to these non-Navigator assistance personnel will therefore ensure that they provide services consistent with this interpretation of § 155.205, and will minimize confusion in the marketplace. We solicit public comments on applying the same conflict-of-interest standards to both

³ HHS, jointly with the Departments of Labor and the Treasury, issued a Request for Information Regarding Stop Loss Insurance on May 1, 2012. See 77 FR 25788. In that Request for Information, we explained that stop loss insurance is designed to protect against health insurance claims that are catastrophic or unpredictable in nature, and that it provides coverage to self-insured group health plans once a certain level of risk has been absorbed by the plan.

Navigators and non-Navigator assistance personnel.

State-based Exchanges would not be required to adopt the conflict-of-interest standards proposed in § 155.215(a) for their Navigators or for their non-Navigator assistance personnel that are not funded through 1311(a) Exchange Establishment grants. However, State-based Exchanges may wish to consider using the standards proposed in § 155.215 as models when developing their own standards.

a. Conflict-of-Interest Standards for Navigators (Proposed § 155.215(a)(1))

Section 1311(i)(4) of the Affordable Care Act directs the Secretary to establish standards for Navigators, including provisions to avoid conflicts of interest. Section 155.210(b)(1) directs all Exchanges to develop and publicly disseminate conflict-of-interest standards for Navigators. The conflict-of-interest standards proposed in § 155.215(a)(1) are intended to apply to all Navigators in Federally-facilitated Exchanges, including State Partnership Exchanges.

Section 155.210(c)(1)(iv) prohibits Navigators from having conflicts of interest during their terms as Navigators. In this context, we have explained that having a conflict of interest means having a private or personal interest sufficient to influence, or appear to influence, the objective exercise of a Navigator's official duties (77 FR 18330–18331). In addition, § 155.210(d) directs that a Navigator must not have certain relationships with insurance issuers or the insurance industry. Because any individual or entity with the conflicts of interest listed at § 155.210(d) would be barred from participating as a Navigator, the first proposed conflict-of-interest standard, as set forth in proposed § 155.215(a)(1)(i), would require that a Navigator entity, including a Navigator grant applicant, submit to the Exchange a written attestation that the Navigator and its staff do not have any of these prohibited conflicts of interest. This disclosure to the Exchange will help to ensure that Navigators comply with the prohibitions on Navigator conduct set forth in § 155.210(d), and that individuals and entities who are ineligible under § 155.210(d) do not apply to the Exchange for grants to serve as Navigators. We solicit public comments on the proposal to require Navigators to submit an attestation regarding eligibility.

Proposed § 155.215(a)(1)(ii) would direct that all Navigator entities submit to the Exchange a written plan to remain free of conflicts of interest during their

term as a Navigator. This plan should ensure that the Navigator grantee, and all those individuals who serve as Navigators under the direction of the Navigator grantee, would fully comply with the prohibitions in § 155.210(d), and all other conflict-of-interest requirements, as described below, throughout the term of a Navigator grant. This would be particularly important for those Navigator entities that may have a changing workforce, and might thus utilize new or different staff or employees during the term of a Navigator grant. We solicit public comments on the proposed requirement to submit a written plan to remain free of conflicts of interest, including comments on the form of and content for the plan.

Proposed § 155.215(a)(1)(iii) would direct that all Navigators, both individual Navigators and Navigator entities, and their staff, provide information to consumers about the full range of QHP options and insurance affordability programs such as premium tax credits and cost sharing reductions and Medicaid and CHIP, for which they are eligible. This proposed requirement would help ensure that consumers receive all of the information they need to make an informed enrollment decision, and that the information they receive is fair, as required by § 155.210(e)(2).

Lastly, the proposed conflict-of-interest standards for Navigators include the requirement at proposed § 155.215(a)(1)(iv) that certain conflicts of interest, while not a bar to serving as a Navigator, should be disclosed to the Exchange and to each consumer receiving application assistance (which includes pre-enrollment and post-enrollment services, but does not include outreach and education assistance), both by the Navigator individual and the entity. In developing the conflict-of-interest standards in the proposed rule, we have been mindful that every Navigator must “provide information and services in a fair, accurate and impartial manner” under § 155.210(e)(2). We have also been mindful that each Exchange must develop standards “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,” § 155.210(b)(1). The requirement that an Exchange develop standards to minimize and mitigate conflicts of interests suggests that some conflicts of interest would not be absolute bars to service as a

Navigator, provided that the conflict of interest would not ultimately prevent the entity or individual from providing information and services in a fair, accurate, and impartial manner. Striking this balance will allow for a robust pool of Navigators, without sacrificing the need to ensure that all Navigators have the integrity, fairness, and impartiality to carry out their duties appropriately.

Under the proposed rule, in order to mitigate conflicts of interest, there are three types of information that Navigators should disclose to the Exchange and to their consumers. First, Navigator and all Navigator staff members would be required to disclose to the Exchange and to each consumer who receives application assistance from the Navigator entity or individual, any lines of insurance business, other than health insurance or stop loss insurance, which the Navigator intends to sell while serving as a Navigator. Since Navigators must not sell health insurance and as we also propose, must not sell stop loss insurance, the proposed requirement that Navigators disclose “any lines of insurance business” is not intended to apply to the sale of health insurance or stop loss insurance, since these are not conflicts of interest that could be mitigated through disclosure (see § 155.210(d)).

In addition, the proposed rule would require disclosure of two other types of indirect financial conflicts of interest. Navigators and their staff members would be required to disclose to the Exchange and each consumer receiving application assistance, any existing and former employment relationships they have had within the last five years with any issuer of health insurance or stop loss insurance, or subsidiaries of such issuers. It is intended that any existing employment relationships disclosed would be non-prohibited relationships, because receipt of any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP would already be prohibited by § 155.210(d)(4). They must also disclose any existing employment relationships between any health insurance issuer or stop-loss insurance issuer, or subsidiary of such issuers, and the individual's spouse or domestic partner. Navigators and their staff members would also be required to disclose to the Exchange and to each consumer receiving application assistance any existing or anticipated financial, business, or contractual relationships with one or more issuers of health insurance or stop loss insurance or subsidiaries of such

issuers. These types of conflict-of-interest relationships with issuers of health insurance or stop loss insurance should be disclosed because these relationships may confer benefits or indirect financial gain that would compromise a Navigator's objectivity. We solicit public comments on the proposed requirement to disclose certain types of potential financial conflicts of interest.

Under existing regulations, a Navigator must not act on behalf of health insurance issuers, either as agents or under appointment, since this would violate the prohibition on conflicts of interest in § 155.210(d)(1) through (d)(3) and the prohibition at § 155.210(d)(4) on receiving compensation from issuers in connection with enrollment. However, we note that agents and brokers have traditionally assisted consumers in obtaining health insurance. We anticipate that agents and brokers will continue to be an important source of assistance for many consumers seeking access to health insurance coverage through an Exchange, including those who own and/or are employed by small businesses. The proposed conflict-of-interest standards for Navigators would permit agents and brokers to serve as Navigators in an Exchange operated by HHS, provided that the agent or broker can satisfy the standards that will apply to all Navigators in the Exchange. For example, as stated above, all Navigators, including agents and brokers serving as Navigators, are prohibited from receiving consideration, directly or indirectly, from any health insurance issuer in connection with the enrollment of consumers into QHPs or non-QHPs (§ 155.210(d)(4)), and we interpret that provision to apply to the receipt of trailer commissions. Under the proposed amendments to § 155.210(d), the same prohibition would apply to agents or brokers receiving consideration from stop loss insurance issuers. Agents and brokers who sell other lines of insurance would not be prohibited from receiving consideration from the sale of those other lines of insurance while serving as Navigators, provided they complied with the disclosure requirement.

If an entity or organization is awarded a grant to be a Navigator, the entity as a whole is considered to be a Navigator. Therefore, the prohibition on receipt of compensation from certain insurance issuers in connection with the enrollment of consumers into QHPs or non-QHPs, would apply to the entire organization and its entire staff. While a Navigator could retain staff members who serve as agents and brokers, those

staff members—and the organization itself—could not receive compensation from health insurance or stop loss insurance issuers for enrolling individuals or employees in QHPs or health insurance plans outside of the Exchange. Such staff members, however, could continue to be compensated for selling other insurance products (for example, auto, life, and homeowners' policies).

We solicit public comments on the proposed conflict-of-interest standards applicable to Navigators.

b. Conflict-of-Interest Standards for Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under § 155.205(d) and (e) (Proposed § 155.215(a)(2))

Proposed § 155.215(a)(2) would establish a set of parallel conflict-of-interest standards that would apply in Federally-facilitated Exchanges (including State Partnership Exchanges) to non-Navigator assistance personnel carrying out consumer assistance functions under 155.205(d) and (e), and to federally-funded non-Navigator assistance personnel in a State-Based Exchange. As discussed above, we believe the same conflict-of-interest considerations that apply to Navigators should also apply to these non-Navigator assistance personnel. With respect to the requirement to submit a mitigation plan under proposed § 155.215(a)(2)(iii), consistent with the requirement that only a Navigator entity (not individual staff) would be required to submit the plan, the mitigation plan would only be required on an individual basis if the individual is not working for an entity serving as non-Navigator assistance personnel.

In addition, the proposed rule would direct that these non-Navigator assistance personnel adhere to and comply with the same restrictions on participation and prohibitions on conduct that apply to Navigators under § 155.210(d). Therefore, like Navigators, individuals and entities performing non-Navigator assistance functions under § 155.205(d) and (e) must not have any of the disqualifying conflicts of interest arising from being an issuer of health insurance or stop loss insurance, a subsidiary of such an issuer, or an association with members that are issuers or that lobbies for health insurance or stop loss issuers, or from receiving compensation from an issuer of health insurance or stop loss insurance in connection with enrollment in QHPs or non-QHPs. We solicit public comments on the application of these proposed standards to non-Navigator assistance personnel.

2. Training Standards for Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 (Proposed § 155.215(b))

Existing regulations at 45 CFR 155.210(b)(2) direct Exchanges to develop and disseminate a set of training standards, to be met by all entities and individuals carrying out Navigator functions. Under § 155.210(b)(2), the training standards developed by the Exchange must ensure Navigator expertise in eligibility and enrollment rules and procedures, the range of QHP options and insurance affordability programs, the needs of underserved and vulnerable populations, and privacy and security requirements applicable to personally identifiable information. In addition, to receive a Navigator grant, § 155.210(c)(1)(iii) directs that an entity or individual must meet any licensing, certification, or other standards prescribed by the state or Exchange, if applicable.

In addition, in the proposed rule relating to Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, published on January 22, 2013 (78 FR 4594, 4710), we proposed an amendment to § 155.205(d) that would require any individual providing consumer assistance under that section, including Navigators, to “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.”

Consistent with the existing requirements in § 155.210(b)(2) and § 155.210(c)(1)(iii) and the proposed requirements at 78 FR 4710, we now propose a specific set of training standards that would require up to 30 hours of training, including standards for certification and recertification, for all Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and all federally funded non-Navigator assistance personnel in State-based Exchanges, to ensure that these entities and individuals can satisfy the duties and obligations of serving as Navigators or non-Navigator assistance personnel. These proposed standards would be

applicable to all Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and to all federally funded non-Navigator assistance personnel in State-based Exchanges, and can be used by State-based Exchanges at their option for their Navigator personnel and non-federally funded non-Navigator assistance personnel.

a. Certification and Recertification Standards (Proposed § 155.215(b)(1))

Section 1311(i)(4) of the Affordable Care Act directs the Secretary to establish standards for Navigators, including provisions to ensure that any private or public entity that is selected as a Navigator is qualified, and licensed if appropriate, to engage in Navigator activities and to avoid conflicts of interest. Under existing regulations at 45 CFR 155.210(c)(1)(iii), Navigators must meet any “licensing, certification or other standards prescribed by the state or Exchange, if applicable.” In addition, we have previously proposed to amend § 155.205(d) to require that any individual providing consumer assistance under § 155.205(d) 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 (78 FR 4594).

We now propose in § 155.215(b)(1) that all Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange or State Partnership Exchange, and federally-funded non-Navigator assistance personnel in a State-Based Exchange, register with the Exchange and be certified by the Exchange, and prior to certification, complete an HHS-approved training before carrying out any consumer assistance functions in the Exchange. We propose in § 155.215(b)(2) the topics about which such Navigators and non-Navigator assistance personnel would receive training prior to certification. The proposed rule would also direct that individuals and staff of Navigator entities and non-Navigator assistance entities receive a passing score on all HHS-approved examinations in order to serve as Navigators or non-Navigator assistance personnel in a Federally-facilitated Exchange, a State Partnership Exchange, or as federally-funded non-Navigator assistance personnel in a State-based Exchange.

The proposed recertification requirement for Navigators and non-Navigator assistance personnel would

ensure that they remain appropriately trained to adequately serve consumers. The rule also proposes that Navigators and non-Navigator assistance personnel should obtain continuing education and be certified and/or recertified on at least an annual basis.

We also propose that these certification requirements would specifically direct that all Navigators and non-Navigator assistance personnel be prepared to serve both the individual Exchange and SHOP in a Federally-facilitated Exchange. Section 1311(i)(2)(A) of the Affordable Care Act directs that, to be eligible to receive a Navigator grant, an entity must demonstrate that it has existing relationships, or could readily establish relationships, with employers and employees. In addition, section 1311(i)(2)(B) directs that the types of entities that may be eligible for a Navigator grant include resource partners of the Small Business Administration. We infer from these standards that Navigators must be prepared to serve the needs of small businesses, and therefore will need to be prepared to serve the needs of both the individual Exchange and SHOP. We also believe that non-Navigator assistance personnel who carry out consumer outreach, assistance, and education in the Exchange and are paid for by Federal funding should be prepared to serve the needs of both the individual Exchange and SHOP. In order to be truly helpful and useful to the public, we believe that services provided under § 155.205(d) and (e) should be available to all consumers, including small businesses. Directing non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and federally funded non-Navigator assistance personnel in State-based Exchanges to provide assistance to all consumers will ensure that they provide services consistent with this interpretation of § 155.205.

Each Navigator and non-Navigator assistance personnel should have the ability to help any individual who presents him or herself for assistance. However, there may be some instances where a Navigator, or non-Navigator assistance personnel, does not have the immediate capacity to help an individual. In such cases, the Navigator or non-Navigator assistance personnel should be capable of providing assistance in a timely manner but should also refer consumers seeking assistance to other Exchange resources, such as the toll-free Exchange Call Center, or to another Navigator or non-Navigator assistance personnel in the

same Exchange who might have better capacity to serve that individual more effectively.

We solicit public comments on these proposed training and certification standards, including the proposed recertification standards.

b. Training Module Content Standards (Proposed § 155.215(b)(2))

Each entity that serves as a Navigator, and each individual that will carry out Navigator functions under the terms of a Navigator grant in a Federally-facilitated Exchange or State Partnership Exchange, must receive training to perform all of the duties of a Navigator. Although different Navigators may perform these duties at different levels of effort or focus, every Navigator must be trained to perform all of the listed duties in section 1311(i)(3) of the Affordable Care Act and in § 155.210(e). Therefore, in order to carry out a Navigator’s duties to maintain expertise in eligibility and facilitate selection of QHPs, all Navigators will receive training so that they are equipped with the necessary information to help consumers apply for coverage through the Exchange, which will ultimately result in an eligibility determination for enrollment in a QHP and/or an insurance affordability program. Non-Navigator assistance personnel must receive comparable training with respect to their specific responsibilities. In addition, Navigators and non-Navigator assistance personnel must receive training on the privacy and security requirements for the protection of personally identifiable information, including relevant state laws.

In addition to training designed to help Navigators and non-Navigator assistance personnel build expertise in eligibility and facilitating selection of QHPs, training for Navigators and non-Navigator assistance personnel should prepare them to educate consumers about the advanced payments of the premium tax credit and cost-sharing reductions and help them submit the appropriate information to receive an eligibility determination for insurance affordability programs, including advanced payments of the premium tax credits and cost-sharing reductions. In addition, Navigators should be trained so that they will be prepared to fulfill the duty at § 155.210(e)(2) to “provide information and services in a fair, accurate and impartial manner,” including the requirement that “such information acknowledge other health programs,” including Medicaid and CHIP. Therefore, § 155.215(b)(2) proposes a set of standards for the content of the training module for

Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange or State Partnership Exchange, and for federally funded non-Navigator assistance personnel in a State-based Exchange, to ensure that they would be knowledgeable in these areas, and fully prepared to assist consumers.

The Exchange regulations, at 45 CFR 155.260(a), establish privacy and security standards for Exchanges, and § 155.260(b) provides that Exchanges must require Navigators and other non-Exchange entities to abide by the same or more stringent privacy and security standards as a condition of contract or agreement with such entities. Consistent with these requirements, we propose that the training for Navigators and non-Navigator assistance personnel must include training designed to ensure that they safeguard consumers' sensitive personal information including but not limited to health information, income and tax information, and Social Security number.

Subsections 155.205(d) and (e) direct Exchanges to conduct consumer assistance, outreach, and education activities, including Navigator programs, in a way that meets the standards set forth at § 155.205(c). Section 155.205(c), in turn, directs Exchanges to provide information to applicants and enrollees in plain language and in a manner that is accessible and timely to individuals living with disabilities and individuals who are limited English proficient (LEP). Additionally, § 155.210(e)(5) directs Navigators to provide information in a manner that is culturally and linguistically appropriate to the needs of the population served by the Exchange, including individuals with limited English proficiency, and to ensure accessibility and usability of Navigator tools and functions for individuals with disabilities. We interpret the foregoing provisions to require all entities and individuals carrying out activities authorized by §§ 155.205(d) and (e) and 155.210, including Navigators and non-Navigator assistance personnel, to be knowledgeable about the special needs of populations with limited English proficiency and people with a full range of disabilities, and how best to communicate with and assist these consumers. The rule therefore proposes that the training for Navigators and non-Navigator assistance personnel would include training designed to ensure that they will be equipped to provide culturally and linguistically appropriate services and ensure physical and other accessibility for people with disabilities.

We solicit public comments on the proposed requirement to receive training regarding culturally and linguistically appropriate services as well as accessibility for people with disabilities.

3. Providing Culturally and Linguistically Appropriate Services (CLAS Standards) (Proposed § 155.215(c))

Proposed § 155.215(c) and (d) detail standards for the use and provision of culturally and linguistically appropriate tools and services as well as requirements to ensure access by individuals with disabilities who seek assistance from Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and from federally-funded non-Navigator assistance personnel in a State-based Exchange.

Section 1311(i)(3)(E) of the Affordable Care Act directs that Navigator entities have a duty to provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange or Exchanges. According to the regulation implementing this provision, Navigators must "provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange, including individuals with limited English proficiency" (§ 155.210(e)(5)). Additionally, all non-Navigator assistance personnel must meet the accessibility standards set forth at § 155.205(c).

Independent of these obligations, certain Federal civil rights laws, such as Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, also apply to Navigators in Federally-facilitated and State Partnership Exchanges. These laws would also apply to non-Navigator assistance programs in State-based and State Partnership Exchanges to the extent such programs receive federal financial assistance. These federal civil rights laws impose nondiscrimination obligations with respect to persons with disabilities and that address the communications needs of persons who have limited English proficiency (LEP).

While the proposed training module content standards discussed earlier in this preamble include a requirement that training include providing culturally and linguistically appropriate services, this proposed rule also provides more specific standards for ensuring meaningful access. These proposed standards should be read

together with all other applicable standards issued by the Secretary related to ensuring meaningful access by individuals with limited English proficiency.

The specific standards proposed in § 155.215(c) include that Navigators and non-Navigator assistance personnel develop, maintain, and regularly update general knowledge about the racial, ethnic, and cultural groups in their service area, including the primary languages spoken, and continue to use this information. The proposed requirements would also include that such entities and individuals provide consumers with information and assistance in the consumer's preferred language, at no cost to the consumer, which would include oral interpretation of non-English languages and the translation of written documents in non-English languages when necessary to ensure meaningful access. We also propose that use of a consumer's family or friends as interpreters can satisfy the requirement to provide linguistically appropriate services only when requested by the consumer as the preferred alternative to an offer of other interpretive services. We anticipate that most Navigators and non-Navigator assistance personnel would use readily available telephonic interpretation services and other effective low-cost services in order to meet the requirement to provide language access to the consumers they serve, so that it will not be costly or onerous.

In addition, § 155.215(c)(4) of the proposed rule would require that non-Navigator assistance personnel provide limited-English-proficiency consumers with oral and written notices informing them of their right to receive language assistance services and how to obtain such services. This requirement could be satisfied using methods outlined in existing § 155.205(c)(2), which allows for the use of taglines in non-English languages placed on documents or Web sites to indicate the availability of language services.

Section 155.215(c)(6) of the proposed rule would also direct Navigator and non-Navigator assistance personnel entities to implement strategies to recruit and promote a staff that is representative of the demographic characteristics, including primary languages spoken, of the communities in their service area.

4. Standards Ensuring Access by Persons With Disabilities (Proposed § 155.215(d))

Section 155.210(e)(5) directs that an entity serving as a Navigator has a duty to "ensure accessibility and usability of

Navigator tools and functions for individuals with disabilities in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.” Similarly, § 155.205(c) requires that persons providing consumer assistance pursuant to § 155.205(d) and (e) provide individuals living with disabilities with information that is accessible at no cost to the individual, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

Additionally, independent of these obligations, certain Federal civil rights laws, such as Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, also apply to Navigators in Federally-facilitated and State Partnership Exchanges. These laws would also apply to non-Navigator assistance programs in State-based and State Partnership Exchanges to the extent such programs receive federal financial assistance. These federal civil rights laws impose nondiscrimination obligations with respect to persons with disabilities and that address the communications needs of persons who have limited English proficiency (LEP).

In accordance with these requirements, § 155.215(d)(2) of the proposed rule would direct that auxiliary aids and services for individuals with disabilities be provided at no cost where necessary for effective communication. The proposal specifies that the use of a consumer’s family or friends as interpreters can satisfy the requirement to provide auxiliary aids and services only when requested by the consumer as the preferred alternative to an offer of other auxiliary aids and services. In addition, proposed section 155.215(d)(3) would require Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange or State Partnership Exchange, and federally-funded non-Navigator assistance personnel in a State-based Exchange to provide assistance to consumers in a location and in a manner that is physically and otherwise accessible to individuals with disabilities. Proposed section 155.215(d)(1) would direct Navigators and non-Navigator assistance personnel to ensure that any consumer education materials, Web sites, or other tools utilized for consumer assistance purposes are accessible to people with disabilities.

Section 155.215(d)(4) of the proposed rule would also require that legally authorized representatives be permitted to assist individuals with disabilities to make informed decisions. Finally, proposed § 155.215(d)(5) would direct that individuals carrying out Navigator

and non-Navigator assistance functions have the ability to refer people with disabilities to local, state, and federal long-term services and supports programs when appropriate. We seek comment on this requirement.

These proposed standards should be read together with all other applicable standards issued by the Secretary related to ensuring meaningful access by people with disabilities.

5. Monitoring (Proposed § 155.215(e))

The proposed rule indicates that Federally-facilitated Exchanges (including State Partnership Exchanges) will monitor compliance with the standards described in § 155.215 and with the requirements described in § 155.205(d) and (e) and 155.210. To the extent possible, these Exchanges will engage in monitoring whether Navigators and non-Navigator assistance personnel comply with those standards, including, for example, reviewing reports filed by Navigators and reviewing the attestations and conflict-of-interest plans required to be submitted to the Exchange as proposed in § 155.215(a)(1)(i) through (ii) and (a)(2)(ii) through (iii) of the proposed regulation; conducting discussions with states in which Navigator grantees and non-Navigator assistance personnel exercise their functions; and reviewing casework and complaints filed with the Exchange or a relevant state. We solicit comments on how monitoring for federally-funded non-Navigator assistance personnel in State-based Exchanges should be conducted.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This proposed rule would establish conflict-of-interest and training standards, including standards for certification and recertification, for Navigators and non-Navigator assistance personnel in an Exchange being operated by HHS as a Federally-facilitated Exchange or as a State Partnership Exchange pursuant to HHS authority under section 1321(c)(1) of the Affordable Care Act and for non-Navigator assistance personnel in State-based Exchanges that are funded through federal Exchange Establishment grants. The proposal requires that these Navigators and non-Navigator assistance personnel provide an attestation that they are not ineligible individuals or entities and submit a plan for mitigating conflicts of interest, register with the Exchange, receive training, be initially certified, and receive subsequent recertification with the Exchange.

Section III.A outlines information collection requirements associated with disclosure of conflicts of interest. These disclosures include an attestation regarding eligibility to be a Navigator or non-Navigator assistance personnel; a plan for mitigating conflicts of interest; a requirement to provide information to consumers about their coverage options; and a requirement to disclose other potential, non-prohibited, conflicts of interest. Section III.B outlines information collection requirements associated with registration, certification, and recertification requirements. We are soliciting public comments on each of these issues for the following sections of the proposed rule that contain information collection requirements (ICRs).

For purposes of the information collection requirements, Navigator personnel and non-Navigator assistance personnel are estimated to have a professional wage of \$20 per hour.⁴ Navigator and non-Navigator assistance project leads are estimated to have a professional wage of \$29 per hour.⁵ Navigator senior executives are estimated to have a professional wage of \$48 per hour.⁶ The average professional wage for Navigator personnel, projects

⁴ These positions are estimated to be equivalent to a GS-9 position with the Federal government. See http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/g_s_h.pdf.

⁵ These positions are estimated to be equivalent to a GS-12 position with the Federal government. See http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/g_s_h.pdf.

⁶ These positions are estimated to be equivalent to a GS-15 position with the Federal government. See http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/g_s_h.pdf.

leads, senior executives, and non-Navigator assistance personnel and project leads is estimated to be \$29.20 per hour.

At this time we are unable to estimate the number of Navigator grantees and applicants or the number of non-Navigator assistance personnel and project leads; therefore the estimates discussed below are on a per individual basis. Additionally, we are unable to estimate the number of consumers expected to receive assistance from Navigator grantees or non-Navigator assistance personnel; therefore estimates for disclosures to consumers discussed below are on a per consumer basis. We invite public comments on the number of Navigator grantees or the number of non-Navigator assistance personnel and project leads expected, as well as the number of consumers expected to receive assistance.

A. ICRs Regarding Disclosure of Conflicts of Interest (Proposed § 155.215(a))

Pursuant to proposed § 155.215(a)(1)(i) & (iv) and (a)(2)(ii) & (v), Navigator program grantees and other entities and individuals providing assistance under §§ 155.205(d) and (e) would be required to disclose conflicts of interest. This disclosure would include an attestation that an individual or entity is not an ineligible entity. Additionally, pursuant to proposed § 155.215(a)(1)(ii) and (a)(2)(iii), a plan for mitigating any conflicts of interest would also be submitted. The cost burden associated with the attestation would apply to each Navigator entity and applicant, and to each individual or entity serving as non-Navigator assistance personnel. The cost burden associated with the plan for mitigating any conflicts of interest will apply to each Navigator program grantee and to each individual or entity serving as non-Navigator assistance personnel.⁷ The attestation and mitigation plan are one-time requirements.

We estimate it will take Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads 0.25 hours (15 minutes) each to prepare and provide the attestation that they are an eligible entity. With a wage of \$20 per hour for Navigator and non-Navigator personnel, \$29 per hour for Navigator and non-Navigator project leads, and \$48 per hour for senior executives, we estimate

the cost burden per Navigator personnel would be \$5, per Navigator project lead would be \$7.25, per Navigator senior executives would be \$12, per non-Navigator assistance personnel would be \$5, and per non-Navigator assistance personnel would be \$7.25. The total burden per person would be 0.25 hours and \$7.30 on average.

The plan for mitigating conflicts of interest would be required on a per entity basis;⁸ therefore we assume for Navigator program grantees, the senior executive would be responsible for developing and providing the plan for mitigating conflicts of interest because only one plan is required per grantee. For purposes of the ICR we are assuming burden and cost estimates based on a non-Navigator assistance project lead wage of \$29 per hour.

We estimate that for a Navigator program grantee it will take a senior executive up to 5 hours to prepare and provide a plan for mitigating conflicts of interest and a non-Navigator assistance project lead would also require up to 5 hours to prepare and provide a plan for mitigating conflicts of interest. With a wage of \$48 per hour for senior executives and \$29 per hour for non-Navigator assistance project leads, we estimate the total one-time annual cost burden for a Navigator program grantee would be \$240, and for non-Navigator assistance project leads would be \$145.

Pursuant to proposed § 155.215(a)(1)(iii) and (a)(2)(iv), Navigator program grantees and non-Navigator assistance personnel would be required to provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible. We assume that the total time to provide this disclosure would be one hour per disclosure. We assume for the Navigator program grantee that the Navigator personnel would prepare the disclosure and the total burden estimated per disclosure would be 1 hour at a cost of \$20. For non-Navigator assistance personnel we estimate the total burden per disclosure would be 1 hour for preparing the disclosure at a cost of \$20. The total burden per disclosure would be 1 hour and \$20 on average.

Pursuant to proposed § 155.215(a)(1)(iv) and (a)(2)(v), Navigator personnel, projects leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads would be required to disclose the Exchange and to consumers: any lines of insurance business, not covered by the restrictions on participation and prohibitions on

conduct in § 155.210(d), which they intend to sell while carrying out the consumer assistance functions; any existing and former employment relationships within the last five years with any health insurance issuers or issuers of stop loss insurance or subsidiaries of health insurance issuers or issuers of stop loss insurance; any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance or subsidiaries of health insurance issuers or issuers of stop loss insurance; and any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance. We estimate the total time to prepare this disclosure would be 0.16 hours (10 minutes). The total cost estimated for preparing this disclosure per Navigator personnel would be \$3.20, per Navigator project lead would be \$4.64, per Navigator senior executive would be \$7.68, per non-Navigator assistance personnel would be \$3.20, and per non-Navigator assistance project lead would be \$4.64. The total burden per person would be 0.16 hours and \$4.67 on average.

B. ICRs Regarding Training and Certification Standards (Proposed § 155.215(b))

1. Registration Prior to Training

Pursuant to proposed § 155.215(b)(1)(ii), Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads would be required to register prior to training. We assume that it will take Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads each 0.25 hours (15 minutes) to register. With a wage of \$20 per hour for Navigator and non-Navigator assistance personnel, \$29 for Navigator and non-Navigator assistance project leads, and \$48 for senior executives, we estimate the total cost burden for Navigator personnel would be \$5, for Navigator project leads would be \$7.25, for Navigator senior executives would be \$12, for non-Navigator assistance personnel would be \$5, and for non-Navigator assistance project leads would be \$7.25. The total burden per person would be 0.25 hours and \$7.30 on average.

⁷ The mitigation plan is only required on an individual basis if the individual is not working for an entity serving as non-Navigator assistance personnel.

⁸ An individual could be serving as an entity.

2. Certification and Recertification

Pursuant to § 155.215(b)(1), Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads would be required to complete a training program to obtain certification consisting of up to 30 hours of training including any approved certification exams. There are recordkeeping requirements associated with the certification and recertification provisions. Each person who receives training would be expected to obtain and maintain a record of certification. Pursuant to § 155.215(b)(1)(iv), Navigator personnel, project leads,

senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads who intend to continue beyond their initial period of performance would be required to be recertified on an annual basis. Each person who receives recertification would be expected to obtain proof of recertification and keep it on file. It is estimated that the time burden associated with maintaining proof of certification or recertification would be 0.016 hours (1 minute); we assume proof will be maintained through electronic copies with minimal cost.

The total cost estimated for maintaining proof of certification or recertification per Navigator would be

\$0.32; per Navigator project lead would be \$0.48; per Navigator senior executive would be \$0.75; per non-Navigator assistance personnel would be \$0.32, and per non-Navigator assistance project lead would be \$0.48. In the initial year the requirement will be to maintain proof of initial certification; in subsequent years the requirement will be to maintain proof of recertification. Because these requirements would be the same time and cost burden we are categorizing them as one annual burden. The total annual burden estimated for maintaining proof of certification or recertification would be 0.016 hours and \$0.47 on average.

TABLE 1—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS, BY RESPONDENT

Proposed regulation section(s)	OMB control No.	Burden per response (hours)	Hourly labor cost of reporting (\$)**	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)
Conflict of Interest Attestation § 155.215(a)(1)(i) & (a)(2)(ii).	0938–New	0.25	29.20	7.30	0
Conflict of Interest Mitigation Plan § 155.215(a)(1)(ii) & (a)(2)(iii) Navigator Senior Executive.	0938–New	5	48	240	0
Non-Navigator Assistance Project Lead	5	29	145	0	
Conflict of Interest Disclosure of Coverage Options § 155.215(a)(1)(iii) & (a)(2)(iv).	0938–New	1	20	20	0
Conflict of Interest Disclosure to Exchange and Consumers § 155.215(a)(1)(iv) & (a)(2)(v).	0938–New16	29.20	4.67	0
Training Registration § 155.215(b)(1)(ii)	0938–New	0.25	29.20	7.30	0
Certification and Recertification § 155.215(b)(1) ..	0938–New	0.016	29.20	0.47	0
Total	424.27	0

** The hourly cost of \$29.20 in certain rows is an average of the professional wages estimated for Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads.

IV. Regulatory Impact Statement

A. Summary

HHS is publishing this proposed rule to implement the protections intended by Congress in the most economically efficient manner possible. HHS has examined the effects of this rule as required by Executive Order 13563 (76 FR 3821, January 21, 2011), Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. OMB has determined that this proposed rule is a “significant regulatory action” under Executive Order 12866. Accordingly, OMB reviewed this proposed rule.

1. Need for Regulatory Action

This proposed regulation would establish conflict of interest, training and certification, and meaningful access standards applicable to Navigator programs in Federally-facilitated Exchanges, including State Partnership Exchanges, non-Navigator assistance programs in State Partnership Exchanges, and non-Navigator assistance programs in State-Based Exchanges that are funded through federal 1311(a) Exchange Establishment grants. The proposed rule would require

that these Navigators and non-Navigator assistance personnel register with and be certified by the Exchange. In addition, the proposed rule would establish standards for Navigators and non-Navigator assistance personnel to ensure meaningful access to their services by individuals with limited English proficiency and individuals with disabilities.

The proposed rule also would amend existing regulations to clarify that Navigators must 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; add entities with relationships with issuers of stop loss insurance, including those who are compensated directly or indirectly by issuers of stop loss insurance in connection with enrollment in QHPs or non-QHPs, to the list of entities ineligible to become Navigators; and clarify that the same ineligibility criteria that apply to

Navigators providing services in any Federally-facilitated Exchange, including State Partnership Exchanges, would also apply to non-Navigator assistance personnel providing assistance in State Partnership Exchanges and federally-funded non-Navigator assistance personnel in State-based Exchanges.

2. Summary of Impacts

The proposed regulations would help ensure that Navigators in Federally-facilitated Exchanges, non-Navigator assistance personnel in State Partnership Exchanges, and federally-funded non-Navigator assistance personnel in State-based Exchanges will be fair and impartial, will be appropriately trained, and will provide services and information in a manner that is accessible to persons with limited English proficiency and persons with disabilities. The proposed rule would also ensure that Navigators 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.

Navigators and non-Navigator assistance personnel would incur costs in order to comply with the provisions of this proposed rule, which would be covered by the Navigator grants and other compensation provided by the Exchange to non-Navigator assistance personnel. HHS anticipates that the impacts of the proposed rule would not be economically significant.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (states and individuals are not included in the definition of "small entity"). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

HHS anticipates that the proposed rule would not have a significant economic impact on a substantial number of small entities. Some of the entities that act as Navigators and non-Navigator assistance personnel may be

small entities and would incur costs to comply with the provisions of this rule. It should be noted that serving as a Navigator or non-Navigator assistance personnel is voluntary, and the cost burden related to registering for accounts, verification of registration, initial online training and certification, continuing education and recertification, conflict of interest notification, and providing assistance to consumers would be covered by the Navigator grants and other compensation provided by the Exchange to non-Navigator assistance personnel. Due to lack of data, HHS is unable to estimate how many small entities would elect to serve as Navigators and non-Navigator assistance personnel. We invite public comments on this issue.

The size threshold for "small" business established by the SBA is currently \$7 million in annual receipts for insurance agencies and brokerages.⁹ As discussed earlier, we anticipate that agents and brokers will continue to be an important source of assistance for many consumers seeking access to health insurance coverage through an Exchange, including those who own and/or are employed by small businesses. The proposed conflict of interest standards for Navigators would permit agents and brokers to serve as Navigators in an Exchange operated by HHS, provided that the agent or broker can satisfy the standards that would apply to all Navigators in the Exchange. Additionally, we anticipate that agents and brokers will also play a role in educating consumers about Exchanges and insurance affordability programs, and in helping consumers receive eligibility determinations, compare plans, and enroll in coverage to the extent permitted by a given state.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)

⁹"Table of Size Standards Matched To North American Industry Classification System Codes," effective January 7, 2013, U.S. Small Business Administration, available at <http://www.sba.gov>.

requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any one year by state, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately \$141 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This proposed rule does not mandate expenditures by state governments, local governments, tribal governments, or the private sector, of \$141 million. The cost burden for Navigators and non-Navigator assistance personnel related to registering for accounts, verification of registration, initial online training and certification, continuing education and recertification and conflict of interest notification would be covered by the Navigator grants and other compensation provided by the Exchange to non-Navigator assistance personnel and would not exceed the UMRA threshold. As discussed previously in the preamble, state-based Exchanges and state partners in State Partnership Exchanges may use section 1311(a) Exchange Establishment grants to fund non-Navigator assistance programs. Section 1311(i)(6) prohibits Exchanges from using section 1311(a) grant funds to fund Navigator grants. Section 1311(a) grant funds, however, may be used to cover the Exchange's cost of administering the Navigator program, including, for example, the cost of Navigator training, grants management, and oversight.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications.

The proposed rule would clarify that any Navigator licensing, certification, or other standards prescribed by the state or Exchange should not prevent the application of the provisions of title I of the Affordable Care Act. An entity or individual would be required to 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.

Throughout the process of developing this proposed regulation, HHS has attempted to balance the states' interests and Congress' intent to provide uniform minimum protections to consumers in every state. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that the Centers for Medicare & Medicaid Services has complied with the requirements of Executive Order 13132 for the proposed regulation in a meaningful and timely manner.

F. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. § 801, et seq.), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information.

List of Subjects in 45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance, Women, and Youth.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 155 as set forth below:

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 1. The authority citation for part 155 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1334, 1402, 1411, 1412, 1413.

■ 2. Section 155.210 is amended by revising paragraphs (c)(1)(iii), (d)(1), (d)(2), and (d)(4) to read as follows:

§ 155.210 Navigator program standards.

* * * * *

(c) * * *

(1) * * *

(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;

* * * * *

(d) * * *

(1) Be a health insurance issuer or issuer of stop loss insurance;

(2) Be a subsidiary of a health insurance issuer or issuer of stop loss insurance;

* * * * *

(4) Receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP.

* * * * *

■ 3. Section 155.215 is added to read as follows:

§ 155.215 Standards applicable to Navigators and non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant.

(a) *Conflict-of-Interest Standards.* The following conflict-of-interest standards apply in an Exchange operated by HHS during the exercise of its authority under 45 CFR 155.105(f) and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act:

(1) *Conflict-of-Interest Standards for Navigators.*

(i) All Navigator entities, including Navigator grant applicants, must submit to the Exchange a written attestation that the Navigator, including the Navigator's staff:

(A) Is not a health insurance issuer or issuer of stop loss insurance;

(B) Is not a subsidiary of a health insurance issuer or issuer of stop loss insurance;

(C) Is not an association that includes members of, or lobbies on behalf of, the insurance industry; and

(D) Will not receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or non-QHP.

(ii) All Navigator entities must submit to the Exchange a written plan to remain free of conflicts of interest during the term as a Navigator.

(iii) All Navigator entities, including the Navigator's staff, must provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible.

(iv) All Navigator entities, including the Navigator's staff, must disclose to the Exchange and to each consumer who receives application assistance from the Navigator:

(A) Any lines of insurance business, not covered by the restrictions on participation and prohibitions on conduct in § 155.210(d), which the Navigator intends to sell while carrying out the consumer assistance functions;

(B) Any existing employment relationships, or any former employment relationships within the last 5 years, with any health insurance issuers or issuers of stop loss insurance or subsidiaries of health insurance issuers or issuers of stop loss insurance, including any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance; and

(C) Any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance.

(2) *Conflict-of-Interest Standards for Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under § 155.205(d) and (e).*

All Non-Navigator entities or individuals authorized to carry out consumer assistance functions under § 155.205(d) and (e) must—

(i) Comply with the prohibitions on Navigator conduct set forth at § 155.210(d).

(ii) Submit to the Exchange a written attestation that the entity or individual:

(A) Is not a health insurance issuer or issuer of stop loss insurance;

(B) Is not a subsidiary of a health insurance issuer or issuer of stop loss insurance;

(C) Is not an association that includes members of, or lobbies on behalf of, the insurance industry; and

(D) Will not receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or non-QHP.

(iii) Submit to the Exchange a written plan to remain free of conflicts of interest while carrying out consumer assistance functions under § 155.205(d) and (e).

(iv) Provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible.

(v) Disclose to the Exchange and to each consumer who receives application assistance from the entity or individual:

(A) Any lines of insurance business, not covered by the restrictions on participation and prohibitions on conduct in § 155.210(d), which the entity or individual intends to sell while carrying out the consumer assistance functions;

(B) Any existing employment relationships, or any former employment relationships within the last five years, with any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance, including any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance; and

(C) Any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance.

(b) *Training standards for Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210.* The following training standards apply in an Exchange operated by HHS during the exercise of its authority under § 155.105(f), and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act.

(1) *Certification and recertification standards.* All individuals or entities who carry out consumer assistance functions under §§ 155.205(d) and (e) and 155.210, including Navigators, must meet the following certification and recertification requirements.

(i) Obtain certification by the Exchange prior to carrying out any consumer assistance functions under §§ 155.205(d) and (e) or 155.210;

(ii) Register for and complete a HHS-approved training;

(iii) Following completion of the HHS-approved training described in paragraph (b)(1)(ii) of this section,

complete and achieve a passing score on all approved certification examinations prior to carrying out any consumer assistance functions under §§ 155.205(d) and (e) or 155.210;

(iv) Obtain continuing education and be certified and/or recertified on at least an annual basis; and

(v) Be prepared to serve both the individual Exchange and SHOP.

(2) *Training module content standards.* All individuals who carry out the consumer assistance functions under §§ 155.205(d) and (e) and 155.210 must receive training in the following subjects:

(i) QHPs (including the metal levels described at § 156.140(b)), and how they operate, including benefits covered, payment processes, rights and processes for appeals and grievances, and contacting individual plans;

(ii) The range of insurance affordability programs, including Medicaid, the Children's Health Insurance Program (CHIP), and other public programs;

(iii) The tax implications of enrollment decisions;

(iv) Eligibility requirements for premium tax credits and cost-sharing reductions, and the impacts of premium tax credits on the cost of premiums;

(v) Contact information for appropriate federal, state, and local agencies for consumers seeking additional information about specific coverage options not offered through the Exchange;

(vi) Basic concepts about health insurance and the Exchange; the benefits of having health insurance and enrolling through an Exchange; and the individual responsibility to have health insurance;

(vii) Eligibility and enrollment rules and procedures, including how to appeal an eligibility determination;

(viii) Providing culturally and linguistically appropriate services;

(ix) Ensuring physical and other accessibility for people with a full range of disabilities;

(x) Understanding differences among health plans;

(xi) Privacy and security standards applicable under § 155.260 for handling and safeguarding consumers' personally identifiable information;

(xii) Working effectively with individuals with limited English proficiency, people with a full range of disabilities, and vulnerable, rural, and underserved populations;

(xiii) Customer service standards;

(xiv) Outreach and education methods and strategies; and

(xv) Applicable administrative rules, processes and systems related to Exchanges and QHPs.

(c) *Providing Culturally and Linguistically Appropriate Services (CLAS Standards).* The following standards will apply in an Exchange operated by HHS during the exercise of its authority under § 155.105(f) and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act. To ensure that information provided as part of any consumer assistance functions under §§ 155.205(d) and (e) or 155.210 is culturally and linguistically appropriate to the needs of the population being served, including individuals with limited English proficiency as required by §§ 155.205(c)(2) and 155.210(e)(5), any entity or individual carrying out these functions must:

(1) Develop and maintain general knowledge about the racial, ethnic, and cultural groups in their service area, including each group's diverse cultural health beliefs and practices, preferred languages, health literacy, and other needs;

(2) Collect and maintain updated information to help understand the composition of the communities in the service area, including the primary languages spoken;

(3) Provide consumers with information and assistance in the consumer's preferred language, at no cost to the consumer, including the provision of oral interpretation of non-English languages and the translation of written documents in non-English languages when necessary to ensure meaningful access. Use of a consumer's family or friends as oral interpreters can satisfy the requirement to provide linguistically appropriate services only when requested by the consumer as the preferred alternative to an offer of other interpretive services;

(4) Provide oral and written notice to consumers with limited English proficiency informing them of their right to receive language assistance services and how to obtain them;

(5) Receive ongoing education and training in culturally and linguistically appropriate service delivery; and

(6) Implement strategies to recruit, support, and promote a staff that is representative of the demographic characteristics, including primary languages spoken, of the communities in their service area.

(d) *Standards ensuring access by persons with disabilities.* The following standards related to ensuring access by people with disabilities will apply in an Exchange operated by HHS during the exercise of its authority under § 155.105(f), and to non-Navigator

assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act. Any entity or individual carrying out any consumer assistance functions under §§ 155.205(d) and (e) or 155.210, and in accordance with § 155.205(c), must:

(1) Ensure that any consumer education materials, Web sites, or other tools utilized for consumer assistance purposes, are accessible to people with disabilities, including those with sensory impairments, such as visual or hearing impairments, and those with mental illness, addiction, and physical, intellectual, and developmental disabilities;

(2) Provide auxiliary aids and services for individuals with disabilities, at no cost, where necessary for effective communication. Use of a consumer's family or friends as interpreters can satisfy the requirement to provide auxiliary aids and services only when requested by the consumer as the preferred alternative to an offer of other auxiliary aids and services;

(3) Provide assistance to consumers in a location and in a manner that is physically and otherwise accessible to individuals with disabilities;

(4) Ensure that legally authorized representatives are permitted to assist an individual with a disability to make informed decisions;

(5) Acquire sufficient knowledge to refer people with disabilities to local, state, and federal long-term services and supports programs when appropriate; and

(6) Be able to work with all individuals regardless of age, disability, or culture, and seek advice or experts when needed.

(e) *Monitoring.* Any Exchange operated by HHS during the exercise of its authority under § 155.105(f) will monitor compliance with the standards in this section and the requirements of §§ 155.205(d) and (e) and 155.210.

Dated: March 13, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 25, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 575

[Docket No. NHTSA-2012-0180]

New Car Assessment Program (NCAP)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Request for comments.

SUMMARY: The U.S. New Car Assessment Program (NCAP) provides comparative information on the safety of new vehicles to assist consumers with vehicle purchasing decisions and encourage motor vehicle manufacturers to make safety improvements. To maintain the relevance and effectiveness of NCAP, NHTSA has periodically updated the program, most recently in model year 2011.

In response to the rapid development of vehicle safety technologies, especially in the area of crash avoidance, the agency is once again requesting public comments in order to help identify the potential areas for improvement to the program that have the greatest potential for producing safety benefits. This notice lists and describes potential areas of study for improving NCAP. The agency will use the comments it receives to aid it in developing a notice proposing near term upgrades to NCAP. The agency will also use the comments received in response to this notice to help it in developing a draft 5-year plan for the NCAP program outlining research that the agency plans to conduct as well as longer term upgrades it intends to pursue making to NCAP.

DATES: You should submit your comments early enough to ensure that Docket Management receives them no later than July 5, 2013.

ADDRESSES: Comments should refer to the docket number above and be submitted by one of the following methods:

- *Federal Rulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery:* 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.

• *Instructions:* For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

• *Privacy Act:* Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78). For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: For crashworthiness issues, you may contact Ms. Jennifer N. Dang, Division Chief, New Car Assessment Program, Office of Crashworthiness Standards (Telephone: 202-493-0598). For crash avoidance and advanced technology issues, you may contact, Mr. Clarke Harper, Crash Avoidance NCAP Coordinator (Telephone: 202-366-1810). For legal issues, you may contact Mr. Steve Wood, Office of Chief Counsel (Telephone: 202-366-2992). You may send mail to any of these officials at the National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., NVS-100, West Building, Washington, DC 20590-0001.

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