

NP and PA Notification of Intent COMMENTS RECEIVED

Date Received	Commenter	Organization Comment/Question	Disposition of Comment/ Rationale
1 3/8/2017	R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM President, American Society of Addiction Medicine	<b>Item 8:</b> The law specifically authorizes NPs and PAs as eligible to apply to be a "Qualifying Other Practitioner." However, the proposed Notification of Intent form asks applicants to certify that they are either an "advanced practice nurse or physician assistant." This difference in terminology may be confusing to potential applicants, as not all advanced practice registered nurses (APRNs) are eligible under the law to apply. NPs are a subset of all APRNs, which also include clinical nurse specialists, nurse anesthetists, and nurse midwives.	SAMHSA agrees with this comment and revised the first attestation in Certification of Qualifying Criteria to read "I certify that I am either a nurse practitioner or physician assistant who satisfies the definition of a 'qualifying other practitioner'..."
		<b>Item 8.</b> The third attestation under Certification of Qualifying Criteria may be confusing as it implies that a State may require NPs or PAs to be supervised AND work in collaboration with a physician.	SAMHSA agrees with the comment and amended the attestation which now reads, "I certify that I am required by State law to be supervised by OR work in collaboration with a qualifying physician to prescribe III, IV, or V medications."
		<b>Item 8:</b> No state currently requires NPs or PAs to be supervised by or work in collaboration with a <i>qualifying</i> physician to prescribe Schedule II, IV, or V medications.	The term is used in the NOI as the CSA requires that NPs and PAs be supervised (or collaborate with) a "qualifying physician" when required by state law to work with a supervising physician (see 21 USC 823(g)(2)(G)(iv)(III)). Moreover, the term "qualifying physician" is specifically defined under 21 USC 823(g)(2)(G)(ii). SAMHSA added a footnote with a definition of the term "qualifying physician" means in the context of the NOI.
		<b>Item 8:</b> The final attestation of this section requires applicants to list the organization (singular) approved to provide the required 24 hours of training. However, the law names eight approved organizations and nowhere does it say NPs or PAs must receive all 24 hours of training from only one organization. Because many applicants may take part of the required 24 hours from one approved organization and other qualifying courses from a different approved organization.	SAMHSA agrees with this comment. The previous NOI required that the practitioner to write-in the name of training provider(s) name(s). The revised NOI allows practitioners to select all applicable training providers from a drop down list.
		<b>Section 8:</b> The second attestation in this section is missing a verb. The draft form shared with ASAM reads, "I certify that I have the capacity to [missing verb] all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification. ASAM recommended that this error be corrected to reflect the statutory language requiring qualifying practitioners to attest to the capacity to provide <i>directly or by referral</i> ."	SAMHSA agrees with this comment and the verb "provide directly or by referral" was added after the word "capacity" and before "all drugs" to the second statement.
2 5/2/2017	Dr. Garry Belkin, Executive Director, New York City Department of Health and Mental Hygiene	<b>Item 2 Address of Primary Practice Location:</b> NPs and PAs often practice at more than one location, and therefore could potentially prescribe buprenorphine at more than one location. Therefore, the form should clarify if only the address of primary practice location is required (as specified in the analogous NOI form for physicians). In addition, it should be clarified if this needs to be the same address that is on a given provider's DEA registration. Furthermore, either on this form or through a separate mechanism, it should be clarified if NPs and PAs are permitted to prescribe at multiple sites as long as the practice arrangements fulfill state requirements for any supervision or collaboration with a qualifying physician.	SAMHSA agrees with comment and added language in NOI's instructions section that practitioners that ensure

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			<p><b>Item 8 Use of term of "Qualifying Physician"</b> The term "qualifying physician" in this section will likely not be clearly understood by applicants; this term should be specifically defined on this form for reference (e.g., is the qualifying physician required to have a buprenorphine waiver or only to meet the qualifying criteria; if the latter, list the qualifying criteria.)</p>	<p>The term is used in the NOI as the CSA requires that NPs and PAs be supervised (or collaborate with) a "qualifying physician" when required by state law to work with a supervising physician (see 21 USC 823(g)(2)(G)(iv)(III)). Moreover, the term "qualifying physician" is specifically defined under 21 USC 823(g)(2)(G)(ii). SAMHSA added a footnote with a definition of the term "qualifying physician" means in the context of the NOI.</p>
			<p><b>Item 8: Use of the term "Supervisory Physician or Collaborative Physicians":</b> The third and fourth criteria in this section are subject to confusion regarding the relationship with a qualifying physician. To our knowledge, there is no provider who is required "to be supervised by <i>and</i> work in collaboration with" a physician. For example, in New York State, a PA is supervised by a physician; by comparison, the word "collaboration" refers to the relationship between an NP and a physician.</p>	<p>SAMHSA agrees with the comment and deleted the word "and" and replaced with the word "OR". It is understood that NPs and PAs may work in collaboration with a "Physician," OR work under the Supervision of a Physician, but not both.</p>
			<p><b>Item 8:</b> The fourth criteria requires the name of the supervisory physician. This wording might create uncertainty for many NPs who have a collaborative relationship with the physician. If the intention is that nurse practitioners also list the name of their collaborating physician, the wording should be changed to say "Supervisory or Collaborating Physician Name."</p>	<p>SAMHSA agrees with the comment and amended the attestation which now reads, "Supervisory OR Collaborative Physician Name."</p>
			<p><b>Item 8:</b> In addition, requiring the applicant to provide the name of the supervisory physician in order to submit the application for a waiver might create delays in providing treatment to patients, and might discourage some from completing the 24 hours of training and/or submitting the application. Some applicants might be in the process of finding an employer, or might experience anticipated or unanticipated changes in employers in the future. Instead of stating the physician name, a provider could attest/he will practice in compliance with the SAMHSA requirement for a supervisory or collaborative qualifying physician, and with their state's supervisory or collaborative practice requirements. If a physician name is determined to be required, then, either on this form or through a separate mechanism, the process by which a PA or NP can update the name of the supervisory or collaborating physician name should be described</p>	<p>SAMHSA does not agreed with the comment. This information is required at the time of submittal. SAMHSA and DEA to process a NOI.</p>
			<p><b>Item 9 Certification of Capacity:</b> The second option needs clarification by adding the intended verb after "capacity to" and before "all drugs."</p>	<p>SAMHSA agrees with this comment and the verb "provide directly or by referral" was added after the word "capacity" and before "all drugs"to the second statement.</p>
			<p><b>Item 10 Certification of Maximum Patient Load:</b> The second option regarding increasing patient load to 100 needs clarification that it refers to second notifications (as specified in the analogous NOI form for physicians).</p>	<p>A second notification was added to the NOI form indicating the the second option regarding increasing patient load to 100 refers to a second notifications (as specified in the analogous NOI form for physicians).</p>
3	5/12/2017	Josanne K. Pagel, MPAS, PA-C, Karuna RMT, DFAAPA President and Chair of the Board, American Association of Physician Assistants	<p><b>Item 2: Address of Practice Location</b> – It is possible Qualifying Other Providers may provide MAT in more than one practice. Accordingly, AAPA recommends the form be adjusted to accommodate the addresses of practice locations.</p>	<p>SAMHSA agrees with comment and added language in NOI's instructions section that practitioners must ensure</p>

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		<p><b>Item 6: Purpose of Notification</b> - The meaning of the bullet, "New Notification, with the intent to immediately facilitate treatment of an individual (one) patient," is not clear. Clarification is requested.</p>	<p>Perhaps the commenter was not able to read the full paragraph pertaining to this section which reads: "New Notification, with the intent to immediately facilitate treatment of an individual (one) patient - an initial notification submitted for the purpose described above, with the additional purpose of notifying the Secretary and the Attorney General of the intent to provide immediate opiate addiction treatment for an individual (one) patient pending processing of this waiver notification."</p>
		<p><b>Item 8 Certification of Qualifying Criteria:</b> The CARA statute specifically authorizes PAs and NPs to be eligible to apply to become a Qualifying Other Practitioner, yet this section asks the practitioner to identify as either an APRN or a PA. AAPA recommends the form comply with the language specified in the statute.</p>	<p>SAMHSA revised the first attestation in Certification of Qualifying Criteria to read "I certify that I am either <b>a nurse practitioner</b> or physician assistant who satisfies the definition of a 'qualifying other practitioner'..."</p>
		<p><b>Item 8:</b> The second and third bullets need to be corrected to read "required to be supervised by or work in collaboration."</p>	<p>SAMHSA agrees with the comment and amended the attestation which now reads, "I certify that I am required by State law to be supervised by OR work in collaboration with a qualifying physician to prescribe III, IV, or V medications."</p>
		<p><b>Item 8:</b> "Qualifying" physician must be removed from the second and third bullets. No State law requires a PA to be supervised or work in collaboration with a "qualifying" physician. If "qualifying" remains in the bullet, the only correct response would be the third bullet, attesting "I certify that I am NOT required by State law to be supervised or work in collaboration with a qualifying physician to prescribe Schedule III, IV, or V medication."</p>	<p>The term is used in the NOI as the CSA requires that NPs and PAs be supervised (or collaborate with) a "qualifying physician" when required by state law to work with a supervising physician (see 21 USC 823(g)(2)(G)(iv)(III)). Moreover, the term "qualifying physician" is specifically defined under 21 USC 823(g)(2)(G)(ii). SAMHSA added a footnote with a definition of the term "qualifying physician" means in the context of the NOI.</p>
		<p><b>Item 8:</b> Request for information on the physician with whom a PA may work in a supervisory or collaborative relationship should be adjusted to read: Supervisory/Collaborative Physician Name: __; Supervisory/Collaborative Physician Phone Number</p>	<p>SAMHSA agrees with the comment and has amended the language to reflect this. The lines now read: "Supervisory/Collaborative Physician Name: __; Supervisory/Collaborative ____"</p>
		<p><b>Item 8:</b> The fifth bullet needs to be adjusted to reflect that a PA may receive training from more than one organization approved for training. Accordingly, organization should be plural, as well as the date(s) of completion.</p>	<p>SAMHSA agrees with this comment. The previous NOI required that the practitioner to write-in the name of training provider(s)' name(s). The revised NOI allows practitioners to select all applicable training providers from a drop down list.</p>
		<p><b>Privacy Act Information Section</b> - This section notes that medical specialty societies be used to verify practitioner credentials. AAPA recommends relevant licensing boards be referenced in place of medical specialty societies.</p>	<p>SAMHSA agrees with the comment and has amended replaced the word "medical specialty societies," with "relevant licensing boards," to reflect this.</p>