ASAM American Society of Addiction Medicine

March 8, 2017

Summer King
SAMHSA Reports Clearance Officer
5600 Fishers Lane, Room 15E57-B
Rockville, Maryland 20857

Dear Ms. King:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 4,300 physicians, physician assistants, nurse practitioners and other clinicians who specialize in addiction treatment, thank you for the opportunity to provide comments on the proposed Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner".

ASAM fully supports the swift and complete implementation of the Comprehensive Addiction and Recovery Act (CARA) (PL 114-198), including Sec. 303 which establishes conditions under which nurse practitioners (NPs) and physician assistants (PAs) may apply to be a "Qualifying Other Practitioner" under 21 USC § 823(g)(2) to prescribe certain approved narcotic treatment medications for the maintenance or detoxification treatment of opioid addiction. While ASAM urges expeditious approval of the Notification of Intent form so that NPs and PAs may begin offering needed addiction treatment services, we do have several concerns with the form as proposed. Our concerns are detailed here by section:

Section 8. Certification of Qualifying Criteria

- 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. While the law gives the Secretary of the

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Department of Health and Human Services (HHS) the authority to revise the requirements for being a qualifying other practitioner and SAMHSA may have proposed this language to accommodate potential changes in the requirements, it may cause confusion in the short run as NPs are currently the only type of APRN eligible to apply. ASAM recommends revising 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'..."

- Secondly, 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. Rather, it is more accurate to say that a State may require NPs or PAs to be supervised OR work in collaboration with a physician. States differ in their scope of practice regulations insofar as they either require collaborative agreements with physicians, require physician supervision, or neither. No state requires both supervision and a collaborative agreement as these regulations would be redundant. Moreover, the attestation conflates State scope of practice laws with the requirement in CARA that NPs and PAs be supervised by or work in collaboration with a *qualifying* physician. No state currently requires NPs or PAs to be supervised by or work in collaboration with a *qualifying* physician to prescribe Schedule II, IV, or V medications. Accordingly, ASAM recommends the third attestation be revised to read "I certify that I am NOT required by State law to be supervised by ***or*** work in collaboration with a ~~qualifying~~ physician..." and "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 *and will be supervised by or work in collaboration with a qualifying physician to prescribe such medications for the treatment of opioid use disorder.*" The following lines that prompt the applicant to list the physician's name and phone number should also be revised to read "Supervisory *or Collaborative* Physician..."
- 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, ASAM recommends this line be revised to say, "Name of ***organization(s)*** approved for training".

Section 9. Certification of Qualifying Capacity

- The second attestation in this section is missing a critical 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,

overdose reversal, and relapse prevention." **ASAM insists this error be corrected to reflect the statutory language requiring qualifying practitioners to attest to the capacity to provide *directly or by referral***. It is essential that the ability to provide *by referral* is included so that the ability to become a qualify practitioner is not limited to NPs and PAs who practice at federally-certified opioid treatment programs (OTPs). Such a restriction would drastically limit the effect of this policy change, would not allow for any expansion of access in areas where OTPs are geographically inaccessible, and – ASAM believes – does not comport with the intent of the law.

Thank you again for the opportunity to provide comment on this important document. ASAM urges OMB to approve the Notification of Intent form with the above recommended changes as quickly as possible.

Sincerely,

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine

NEW YORK CITY DEPARTMENT OF
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May 1, 2017

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Re: Proposed Project: Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner" ***(OMB Docket No. 0930-0369)***

Dear Ms. King:

The New York City Department of Health and Mental Hygiene submits the following comments on the Notification of Intent " (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner."

The New York City (NYC) Department of Health and Mental Hygiene (DOHMH) is a recognized leader in addressing the public health crisis of opioid analgesic overdose deaths. We recognize that increasing access to buprenorphine treatment for opioid use disorder is a critical component of a comprehensive public health approach to the problem. One of DOHMH's key initiatives to increase access to treatment is a buprenorphine training and technical assistance initiative through which 1,500 NYC prescribers will be trained and offered technical assistance. We applaud the Comprehensive Addiction and Recovery Act of 2016, which establishes criteria for nurse practitioners (NPs) and physician assistants (PAs) to qualify for a waiver to prescribe buprenorphine – a crucial strategy to increase buprenorphine prescribing and access to effective treatment. We are including NPs and PAs (in addition to physicians) in our waiver trainings, and are committed to supporting this workforce expansion. Below are key recommendations for enhancing the clarity of the information to be collected using the NOI form to facilitate efficient application for and attainment of buprenorphine waivers by NPs and PAs:

Item 2: Address of Practice Location
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.

Item 8: Certification of Qualifying Criteria
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.)

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 *and* 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.

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."

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 s/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.

Item 9: Certification of Capacity
The second option needs clarification by adding the intended verb after "capacity to" and before "all drugs."

Item 10: Certification of Maximum Patient Load
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).

Thank you for the opportunity to weigh in on this proposed data collection.

Sincerely,

Gary Belkin, MD, PhD
Executive Deputy Commissioner
New York City Department of Health and Mental Hygiene

AAPA

May 12, 2017

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New Executive Office Building, Room 10102
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RE: 2016-28569

On behalf of more than 115,000 PAs (physician assistants), the American Academy of PAs (AAPA) appreciates the opportunity to provide comments on the proposed "Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a 'Qualifying Other Provider.'"

Acutely aware that the abuse, diversion, morbidity, and mortality associated with the opioid epidemic are devastating families and communities across our nation, AAPA appreciates that the administration exercised the flexibility granted through the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) to swiftly implement the waiver process for PAs to apply to be a Qualifying Other Practitioner to prescribe buprenorphine for the treatment of opioid addiction. Additionally, AAPA encourages the administration to exercise the flexibility offered by CARA regarding the requirement that a physician with whom a PA works in a supervisory or collaborative relationship, also be waivered to prescribe buprenorphine. We are very concerned this requirement may erect barriers for experienced PAs who do not affiliate with a waivered physician, particularly in rural and other medically underserved communities in which the capacity of medication assisted treatment (MAT) is severely limited.

AAPA's comments on the proposed waiver form are identified as follows:

Section 2: Address of Practice Location – 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.

Section 6: Purpose of Notification – 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.

Section 8: Certification of Qualifying Criteria – This section contains several errors that need to be corrected.

- 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.
- The second and third bullets need to be corrected to read "required to be supervised by or work in collaboration..."
- "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."
- 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: _____
- 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.

Section 9: Certification of Capacity – A verb is missing in the second bullet, which reads, "I certify that I have the capacity to all drugs approved by the ...." This should be adjusted to read, "I certify that I have the capacity to prescribe all drugs approved by the ..." Additionally, this bullet should be corrected to reflect the statutory language requiring qualifying practitioners to attest "to the capacity to provide directly or by referral." The current language omits referral.

Privacy Act Information – 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.

AAPA appreciates the work of the Substance Abuse and Mental Health Services Administration and the Office of Management and Budget in implementing the provisions of CARA in such a way that PAs may quickly contribute to providing MAT for individuals suffering from opioid addiction. AAPA is committed to finding ways to combat opioid addiction in the U.S., and we look forward to working with you.

Should you have any questions or require additional information regarding AAPA's comments, please do not hesitate to contact Tate Heuer, Vice President for Advocacy, at 571-319-4338 or theuer@aapa.org.

Sincerely,

Josanne K. Pagel, MPAS, PA-C, Karuna RMT, DFAAPA
President and Chair of the Board