07/25/2016

Director, Regulations Management (02REG)
Department of Veterans Affairs
810 Vermont Avenue, NW
Room 1068
Washington, DC 20420

Re: RIN 2900-AP44 Advanced Practice Registered Nurses

The National Conference of State Legislatures (NCSL), submits the following comments on the proposed rule published in the May 25, 2016 Federal Register “Advanced Practice Registered Nurses (APRNs)” (RIN 2900–AP44). NCSL recognizes and appreciates the crucial role APRNs play in the delivery of healthcare across the United States and within the Veterans Administration (VA) Health System. However, NCSL does not support this NPRM and the preemption of state laws regarding the scope of practice for APRNs.

NCSL is concerned that the NPRM proposes to preempt state laws governing the scope of practice of APRNs without consulting state and local elected officials as required by Executive Order (EO) 13132. This EO directs federal agencies to consult with intergovernmental partners from states, including state and locally elected officials, before actions are taken and in the development of standards. I have attached a copy of the EO that lays out in Sec. 3 how federal agencies are expected to carry out the provisions of the order as it relates to states for your review. The most important provision, as it relates to the preemption of state law regarding the practice of nurse practitioners says,

“(b) National action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Where there are significant uncertainties as to whether national action is authorized or appropriate, agencies shall consult with appropriate State and local officials to determine whether Federal objectives can be attained by other means. (c) With respect to Federal statutes and regulations administered by the States, the national government shall grant the States the maximum administrative discretion possible. Intrusive Federal oversight of State administration is neither necessary nor desirable.”

The NPRM implies that state laws regarding the regulation of health professionals can simply be overturned by federal regulation. NCSL does not believe this to be the case. As recently as Friday, July 22, 2016, President Obama signed S. 524, the Comprehensive Addiction and Recovery Act of 2016 (CARA) into law. This law will permit nurse practitioners (NPs) and physician assistants to dispense certain drugs for maintenance or detoxification treatment in office-based settings for up to 30 patients in
the first year and up to 100 patients after the first year and thereafter. The law also provides that for either the NP or the PA to provide these services they must: (1) be licensed under state law to prescribe the medications; (2) complete additional training as provided for in the law; and (3) be supervised or work in collaboration with a "qualified physician" as defined in the statute, if state law requires the NP or PA to be supervised or to work in collaboration with a physician to prescribe medications for the treatment of opioid use disorder. In this case, Congress and the administration recognize and support state law. We believe this is a process that works for both the federal government and the states. NCSL looks forward to working with the Veterans Administration and the other federal agencies involved in the implementation of CARA.

We look forward to working with the Veterans Administration on the implementation of CARA and other veteran’s health issues and hope that in the future you will consider NCSL and state legislators a resource and a partner on these issues.

Sincerely,

Joy Johnson Wilson  
Director, Health & Human Services Policy  
National Conference of State Legislatures
Executive Order 13132 of August 4, 1999

Federalism

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to guarantee the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution, to ensure that the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies, and to further the policies of the Unfunded Mandates Reform Act, it is hereby ordered as follows:

Section 1. Definitions. For purposes of this order:

(a) "Policies that have federalism implications" refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

(b) "State" or "States" refer to the States of the United States of America, individually or collectively, and, where relevant, to State governments, including units of local government and other political subdivisions established by the States.

(c) "Agency" means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5).

(d) "State and local officials" means elected officials of State and local governments or their representative national organizations.

Sec. 2. Fundamental Federalism Principles. In formulating and implementing policies that have federalism implications, agencies shall be guided by the following fundamental federalism principles:

(a) Federalism is rooted in the belief that issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people.

(b) The people of the States created the national government and delegated to it enumerated governmental powers. All other sovereign powers, save those expressly prohibited the States by the Constitution, are reserved to the States or to the people.

(c) The constitutional relationship among sovereign governments, State and national, is inherent in the very structure of the Constitution and is formalized in and protected by the Tenth Amendment to the Constitution.

(d) The people of the States are free, subject only to restrictions in the Constitution itself or in constitutionally authorized Acts of Congress, to define the moral, political, and legal character of their lives.

(e) The Framers recognized that the States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy.
(f) The nature of our constitutional system encourages a healthy diversity in the public policies adopted by the people of the several States according to their own conditions, needs, and desires. In the search for enlightened public policy, individual States and communities are free to experiment with a variety of approaches to public issues. One-size-fits-all approaches to public policy problems can inhibit the creation of effective solutions to those problems.

(g) Acts of the national government—whether legislative, executive, or judicial in nature—that exceed the enumerated powers of that government under the Constitution violate the principle of federalism established by the Framers.

(h) Policies of the national government should recognize the responsibility of—and should encourage opportunities for—individuals, families, neighborhoods, local governments, and private associations to achieve their personal, social, and economic objectives through cooperative effort.

(i) The national government should be deferential to the States when taking action that affects the policymaking discretion of the States and should act only with the greatest caution where State or local governments have identified uncertainties regarding the constitutional or statutory authority of the national government.

Sec. 3. Federalism Policymaking Criteria. In addition to adhering to the fundamental federalism principles set forth in section 2, agencies shall adhere, to the extent permitted by law, to the following criteria when formulating and implementing policies that have federalism implications:

(a) There shall be strict adherence to constitutional principles. Agencies shall closely examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and shall carefully assess the necessity for such action. To the extent practicable, State and local officials shall be consulted before any such action is implemented. Executive Order 12372 of July 14, 1982 ("Intergovernmental Review of Federal Programs") remains in effect for the programs and activities to which it is applicable.

(b) National action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Where there are significant uncertainties as to whether national action is authorized or appropriate, agencies shall consult with appropriate State and local officials to determine whether Federal objectives can be attained by other means.

(c) With respect to Federal statutes and regulations administered by the States, the national government shall grant the States the maximum administrative discretion possible. Intrusive Federal oversight of State administration is neither necessary nor desirable.

(d) When undertaking to formulate and implement policies that have federalism implications, agencies shall:

1) encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States;

2) where possible, defer to the States to establish standards;

3) in determining whether to establish uniform national standards, consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority; and

4) where national standards are required by Federal statutes, consult with appropriate State and local officials in developing those standards.
Sec. 4. Special Requirements for Preemption. Agencies, in taking action that preempts State law, shall act in strict accordance with governing law.

(a) Agencies shall construe, in regulations and otherwise, a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.

(b) Where a Federal statute does not preempt State law (as addressed in subsection (a) of this section), agencies shall construe any authorization in the statute for the issuance of regulations as authorizing preemption of State law by rulemaking only when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that the Congress intended the agency to have the authority to preempt State law.

(c) Any regulatory preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.

(d) When an agency foresees the possibility of a conflict between State law and Federally protected interests within its area of regulatory responsibility, the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.

(e) When an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.

Sec. 5. Special Requirements for Legislative Proposals. Agencies shall not submit to the Congress legislation that would:

(a) directly regulate the States in ways that would either interfere with functions essential to the States' separate and independent existence or be inconsistent with the fundamental federalism principles in section 2;

(b) attach to Federal grants conditions that are not reasonably related to the purpose of the grant; or

(c) preempt State law, unless preemption is consistent with the fundamental federalism principles set forth in section 2, and unless a clearly legitimate national purpose, consistent with the federalism policymaking criteria set forth in section 3, cannot otherwise be met.

Sec. 6. Consultation.

(a) Each agency shall have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. Within 90 days after the effective date of this order, the head of each agency shall designate an official with principal responsibility for the agency's implementation of this order and that designated official shall submit to the Office of Management and Budget a description of the agency's consultation process.

(b) To the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, and that is not required by statute, unless:

(1) funds necessary to pay the direct costs incurred by the State and local governments in complying with the regulation are provided by the Federal Government; or

(2) the agency, prior to the formal promulgation of the regulation,

(A) consulted with State and local officials early in the process of developing the proposed regulation;
(B) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency’s prior consultation with State and local officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and

(C) makes available to the Director of the Office of Management and Budget any written communications submitted to the agency by State and local officials.

(c) To the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation,

(1) consulted with State and local officials early in the process of developing the proposed regulation;

(2) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency’s prior consultation with State and local officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and

(3) makes available to the Director of the Office of Management and Budget any written communications submitted to the agency by State and local officials.

Sec. 7. Increasing Flexibility for State and Local Waivers.

(a) Agencies shall review the processes under which State and local governments apply for waivers of statutory and regulatory requirements and take appropriate steps to streamline those processes.

(b) Each agency shall, to the extent practicable and permitted by law, consider any application by a State for a waiver of statutory or regulatory requirements in connection with any program administered by that agency with a general view toward increasing opportunities for utilizing flexible policy approaches at the State or local level in cases in which the proposed waiver is consistent with applicable Federal policy objectives and is otherwise appropriate.

(c) Each agency shall, to the extent practicable and permitted by law, render a decision upon a complete application for a waiver within 120 days of receipt of such application by the agency. If the application for a waiver is not granted, the agency shall provide the applicant with timely written notice of the decision and the reasons therefor.

(d) This section applies only to statutory or regulatory requirements that are discretionary and subject to waiver by the agency.

Sec. 8. Accountability.

(a) In transmitting any draft final regulation that has federalism implications to the Office of Management and Budget pursuant to Executive Order 12866 of September 30, 1993, each agency shall include a certification from the official designated to ensure compliance with this order stating that the requirements of this order have been met in a meaningful and timely manner.

(b) In transmitting proposed legislation that has federalism implications to the Office of Management and Budget, each agency shall include a certification from the official designated to ensure compliance with this order that all relevant requirements of this order have been met.
(c) Within 180 days after the effective date of this order, the Director of the Office of Management and Budget and the Assistant to the President for Intergovernmental Affairs shall confer with State and local officials to ensure that this order is being properly and effectively implemented.

Sec. 9. Independent Agencies. Independent regulatory agencies are encouraged to comply with the provisions of this order.

Sec. 10. General Provisions.

(a) This order shall supplement but not supersede the requirements contained in Executive Order 12372 ("Intergovernmental Review of Federal Programs"), Executive Order 12866 ("Regulatory Planning and Review"), Executive Order 12988 ("Civil Justice Reform"), and OMB Circular A-19.

(b) Executive Order 12612 ("Federalism"), Executive Order 12875 ("Enhancing the Intergovernmental Partnership"), Executive Order 13083 ("Federalism"), and Executive Order 13095 ("Suspension of Executive Order 13083") are revoked.

(c) This order shall be effective 90 days after the date of this order.

Sec. 11. Judicial Review. This order is intended only to improve the internal management of the executive branch, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

William Clinton

THE WHITE HOUSE,
August 4, 1999.