

CRNA, APRN Full Practice Authority: Support Continues to Grow

On May 25, 2016, the Department of Veterans Affairs issued a proposed rule that, if finalized, would grant Full Practice Authority (FPA) to all Advanced Practice Registered Nurses (APRNs), including Certified Registered Nurse Anesthetists (CRNAs). Before, during, and after the public comment period, which concluded on July 25, numerous organizations and current and former policy-makers have continued to support the full implementation of the proposed rule and legislation which would provide Full Practice Authority to all APRNs (S. 2279/H.R. 1247). Both the rule and this legislation are critical steps toward expanding access to care for Veterans who put their life on the line for our country.

Organizational Support

AARP

For years, AARP has strongly supported efforts to improve consumers' access to healthcare by removing barriers to services provided by nurse practitioners, certified registered nurse anesthetists (CRNAs), certified nurse-midwives, and clinical nurse specialists... On behalf of our nearly 38 million members, including 3.5 million veterans, we urge you to promptly finalize this proposed rule as a means of improving access to and choice of all four types of advanced practice registered nurses (APRNs).

--AARP Comment Letter, July 19, 2016

Air Force Sergeants Association (AFSA) and Iraq and Afghanistan Veterans of America (IAVA)

The undersigned organizations dedicated to the well-being of our nations Veterans are writing to express support for the Veterans Health Administrations (VHA) efforts to finalize a rule recognizing the full practice authority of all advanced practice registered nurses, including CRNAs serving in the VHA pursuant to evidence based recommendations from both the, Commission on Care in its Final Report to Congress and the Department of Veterans Affairs independent assessment of the Health Care Delivery Systems and Management Processes of the Department of Veterans Affairs.

--AFSA and IAVA Comment Letter, July 25, 2016

American Hospital Association (AHA)

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) fully supports the Department of Veterans Affairs' (VA) proposed rule that would allow all advanced practice nurses (APRNs) – nurse practitioners, certified registered nurse anesthetists, certified nurse midwives and clinical nurse specialists – to practice to the full extent of their education and training. This proposal is critical to ensuring that an adequate supply of quality licensed health providers is available to care for the more than 9 million veterans served annually by the VA system.

--AHA Comment Letter, July 22, 2016

AMVETS

AMVETS supports providing full practice authority to advanced practice registered nurses (APRNs), physician assistants (PAs), and other licensed VA health care professionals to allow them to provide care to the full extent of their training. VA has an access to care issue. This is a zero cost solution that would provide veterans with the access, continuity and quality of care, and reduce wait times for veterans needing care.

--Testimony before the Senate Veterans Affairs Committee, June 29, 2016

Independent Recommendations

Commission on Care

VHA is also currently failing to optimize use of advanced practice registered nurses (APRNs). APRNs are clinicians with advanced degrees who provide primary, acute, and specialty health care services.

The Commission Recommends That. . .

- *VHA increase the efficiency and effectiveness of providers and other health professionals and support staff by adopting policies to allow them to make full use of their skills.*

--Commission on Care Report to Congress, July 6, 2016

Independent Assessment of Health Care Delivery Systems and Management Processes of the VA (RAND Corporation)

Formalizing full practice authority for APNs would likely be a cost-effective approach to increasing the productivity of VA's existing workforce.

National Academy of Medicine (formerly the Institute of Medicine)

Recommendation 1: Remove scope-of-practice barriers. Advanced practice registered nurses should be able to practice to the full extent of their education and training.

--IOM Report: The Future of Nursing: Leading Change, Advancing Health

Congressional Support

Former Senator Bob Dole (R-KS)

My commitment to veterans is just one of many reasons I support the proposed rule by the U.S. Department of Veterans Affairs (VA) to grant full practice authority to advanced practice registered nurses (APRNs) in VA facilities—helping to ensure access to timely, quality healthcare for military veterans like myself.

--Forbes Op-Ed, August 11, 2016

Senator Jeff Merkley (D-OR)

The VA has struggled to recruit and retain physician assistants and nurse practitioners, which has exacerbated the issues already plaguing the VA system. The Veterans Health Care Staffing Improvement Act directly addresses this problem by reducing bureaucratic barriers and granting full practice authority to highly-trained medical professionals, which will make it easier for VA facilities across the nation to provide our veterans with the high quality care they need and deserve.

--Press Release, November 10, 2015

Senator Mike Rounds (R-SD)

"I'm pleased the VA recognizes the need to cut down on unnecessary red tape that is preventing our veterans from receiving adequate and timely care," said Rounds. "By easing unnecessary restrictions placed on APRNs [Advanced Practice Registered Nurses] within the VA system, veterans in South Dakota and across the country will have increased access to health care and have the ability to receive that care closer to home. I thank my

United States Senate

WASHINGTON, DC 20510

May 5, 2015

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

We support the work being done in the Veterans Administration (VA) to respond to the increasing healthcare demands of our Veterans by updating the Veterans Health Administration's (VHA) Nursing Handbook. Our understanding it that the VA is considering granting Advanced Practice Registered Nurses (APRNs) recognition as full practice providers in the VHA. This designation would help improve veterans' access to the high quality healthcare they have earned.

APRNs are highly skilled practitioners with expertise in the diagnosis and treatment of illness and the delivery of evidence-based nursing interventions. APRNs include Nurse Practitioners, Certified Registered Nurse Anesthetists, Certified Nurse Midwives, and Clinical Nurse Specialists. As full practice providers, APRNs will provide care to the full scope of their education and skills giving the VHA greater flexibility to utilize all providers within the healthcare team, maximize existing resources, and improve access to high quality care. Decades of research have shown that APRNs provide safe, high quality healthcare in all settings and with all patient populations. This proposal is consistent with the evidenced-based recommendations advanced by the Institute of Medicine in its report, *The Future of Nursing: Leading Change, Advancing Health*, and will allow for greater team-based clinical practice.

We commend your commitment to improving access to exceptional services in the VHA and believe granting APRNs recognition as full practice providers is an important step toward achieving this goal.

Thank you for your consideration.

Sincerely,



Richard J. Durbin
United States Senator



Sherrod Brown
United States Senator



Jon Tester
United States Senator



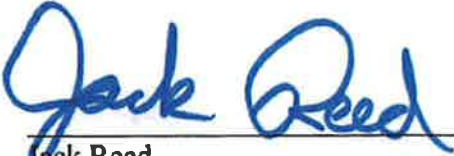
Ed Markey
United States Senator



Sheldon Whitehouse
United States Senator



Jeanne Shaheen
United States Senator



Jack Reed
United States Senator

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United States Senate

WASHINGTON, DC 20510

September 30, 2016

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:


We write to express our support for the proposed rule granting Full Practice Authority (FPA) to all Advanced Practice Registered Nurses (APRNs), including Certified Registered Nurse Anesthetists (CRNAs), serving in the Veterans Health Administration (VHA) and to urge you to finalize and begin implementation of this policy without delay. This rule will allow the VHA to implement evidence-based recommendations from both the blue-ribbon Commission on Care and the independent assessments of the Department of Veterans Affairs (VA) to help improve access to high-quality care for our nation's veterans.

Adopting such a policy is consistent with the evidence-based recommendations proposed by the Institute of Medicine in its report, *The Future of Nursing: Leading Change, Advancing Health*, as well as current APRN policies in the Army, Navy, Air Force, Combat Support Hospitals, and Forward Surgical Teams. Additionally, the proposal is supported by organizations such as AARP, the American Hospital Association, and Veterans Service Organizations, such as IAVA, AmVets, the Military Officers Association of America, the Air Force Sergeants Association, and the Naval Enlisted Reserve Association.

CRNAs are highly skilled practitioners who provide safe and effective delivery of anesthesia care and pain management across all settings and patient populations. As the VA works to improve access to care in all delivery settings, it is imperative that policies are implemented that utilize providers to the full extent of their education and training.

Thank you for your time and consideration on this important matter. Granting all APRNs, including CRNAs, recognition as FPA providers is an important step toward achieving our shared goals of improving timely access to high-quality health care services within the VHA.

Sincerely,



Jack Reed
United States Senator

Sheldon Whitehouse
United States Senator

July 25, 2016

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

The undersigned organizations dedicated to the well-being of our nations Veterans are writing to express support for the Veterans Health Administrations (VHA) efforts to finalize a rule recognizing the full practice authority of all advanced practice registered nurses, including CRNAs serving in the VHA pursuant to evidence based recommendations from both the, Commission on Care in its Final Report to Congress and the Department of Veterans Affairs independent assessment of the Health Care Delivery Systems and Management Processes of the Department of Veterans Affairs.

This policy would not only help address the increasing healthcare demands of our nations Veterans, but would also improve and standardize high quality healthcare delivery, improving the efficiency of our VHA system. Most importantly, recognizing APRNs as FPA providers would improve Veterans' access to the highest quality care and make optimal use of existing VHA personnel.

APRNs are highly skilled practitioners with expertise in the diagnosis and treatment of illness and the delivery of evidence-based nursing interventions. APRNs include Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMs) and Clinical Nurse Specialists (CNSs). CRNAs and other APRNs will provide care to the full scope of their education and skills giving the VHA greater flexibility to utilize all providers within the healthcare team, maximize existing resources, and in turn improve access to high quality care.

Decades of research shows that APRNs provide safe high quality healthcare in all settings and with all patient populations. This proposal is also consistent with the evidenced based recommendations advanced by the Institute of Medicine in their report, *The Future of Nursing: Leading Change, Advancing Health*, current APRN policies in the Army, Navy, Air Force, Combat Support Hospitals and Forward Surgical teams, and will allow for greater team based clinical practice.

Our organizations commend your commitment to improving access to exceptional services within the VHA, and believe adopting this important proposal is a positive step toward achieving this goal. We urge the VHA to finalize and begin implementation of this policy for all four APRN provider types, including CRNAs, to improve Veterans access to the highest quality health care they have earned and deserve.

Thank you for your time and consideration on this important matter.

Sincerely,



Paul Rieckhoff
Founder and CEO
Iraq and Afghanistan Veterans of America (IAVA)



Robert Frank
Chief Executive Officer
Air Force Sergeants Association (AFSA)





STATEMENT FOR THE RECORD

MILITARY OFFICERS ASSOCIATION OF AMERICA

on

Pending Health Care and Benefits Legislation

1st Session, 114th Congress

SENATE COMMITTEE on VETERANS AFFAIRS

June 3, 2015

Such a technical change is important as it takes into consideration the care needed for the veteran and the capabilities of VA medical facilities. MOAA believes requiring a veteran residing within the 40 mile drive time to use a VA medical facility that does not provide the necessary medical care or services is impractical and not in the best interest of the veteran. This provision allows veterans to access care at a medical facility that is able to provide the needed care.

MOAA supports S. 207.

S. 297, Frontlines to Lifelines Act of 2015

MOAA recognizes the challenges faced by the VA in hiring qualified medical professionals to effectively address quality and access to care issues, as well as the particular employment and State credentialing challenges experienced by enlisted medical technicians, combat medics or corpsman before leaving active duty service.

Senator Mark Kirk's (R-IL) bill addresses both of these challenges. The bill seeks to revive and expand the Intermediate Care Technician Pilot Program of the VA. The program would cover a three-year period and include not less than 250 intermediate care technicians. The VA Secretary would be required to assign these technicians to priority medical facilities where veterans have the longest wait times for hospital care or medical service appointments.

Additionally, the provision authorizes the VA to allow covered nurses in certain specialties to practice independently, without supervision or direction of others, under a set of privileges approved by the Secretary, regardless of the State in which the covered nurse is employed by the VA. While MOAA generally supports this section of the provision, we are concerned that the Act excludes Certified Registered Nurse Anesthetists (CRNAs) from the list of covered nurse specialties given full practice authority. Including this specialization further enhances VA's capabilities and goes a long way in addressing the critical advances needed to improve veterans' access to care.

According to the American Association of Nurse Anesthetists, veterans, nurse organizations and the AARP all support full practice authority for CRNAs. Further, such change would also be consistent with current Department of Defense (DoD) practices.

MOAA supports S. 297 with one addition. We recommend that the "Certified Registered Nurse Anesthetist" be added to the list of covered specializations on SEC. 4 (b).

S. 425, Homeless Veterans Reintegration Programs Reauthorization Act of 2015 and S. 684, Homeless Veterans Prevention Act of 2015

Senators John Boozman's (R-AR) and Jon Tester's (D-MT) bill, S. 425, would reauthorize Department of Veterans Affairs (VA) homeless veterans reintegration programs through FY 2020. The legislation is directed at expediting the reintegration of veterans into the labor force, clarifying that veterans who receive housing assistance under the Department of Housing and Urban Development's Veterans Affairs Supportive Housing (HUD-VASH) Program and Native American veterans participating in the Native American Housing Assistance program, are eligible to receive job training under the Homeless Veteran Reintegration Program (HVRP).

HEY 15530 Draft Legislation on the Veterans Health Act of 2015

The Veterans Health Act of 2015 combines important provisions included in Senator Heller's S. 114, "Veterans Affairs Research Transparency Act of 2015," Senator Tester's, S. 172 and 603, "Access to Appropriate Immunizations for Veterans Act of 2015 and Rural Veterans Travel Enhancement Act of 2015," Senator Moran's, S. 398, "Chiropractic Care Available to All Veterans Act of 2015," bills. MOAA provides the following comments and recommendations on selected sections of the proposal for consideration:

Immunizations for Veterans

MOAA supports SEC 2 and endorsed Senator Tester's provision in a February 25, 2015 letter. This legislation will ensure veteran access to appropriate vaccinations for immunization against infectious diseases, supporting the recommended adult immunization schedule established by the Secretary of Health and Human Services. Establishing quality measures and metrics to ensure veterans receive immunizations at appropriate times is an important issue. This measure offers not only peace of mind to veterans by eliminating one additional medical procedure a veteran or family member must track, but also goes a long way in improving the quality of care within the VA health system and the quality of life of our veterans and their families.

MOAA supports SEC 2 of the draft bill.

Chiropractic Care

SEC 3 of the draft bill would expand the provision of chiropractic care and services to veterans. DoD provides for such services in its health system and establishing the requirement in law in VA's health system will allow for consistency and continuity of care between the two systems, particularly for servicemembers requiring such services upon separation from the military.

MOAA supports SEC 3 of the draft provision.

Veterans Affairs Research

MOAA has long supported improved data sharing between the VA and DoD. SEC. 5 of draft bill requires VA to establish a website to allow public access to VA research and improved data sharing between the Departments. This provision is in line with MOAA's 2015 major legislative priorities for veterans health care as well as, what we believe is the intent of the Military Compensation and Retirement Modernization Commission (MCRMC) under the Recommendation 8 section of the report—to improve collaboration between the VA and DoD (Page 127). Synchronizing and making public research conducted in the VA is essential to the long-term sustainability of the veterans and military health systems. MOAA believes a change to SEC 5 (c) (2), (4) and (5) should be made in the list of research topics—by changing the term "Armed Forces" to "Uniformed Services" to enable the U.S. Public Health Service and NOAA Corps to be included in research outcomes.

MOAA supports SEC 5 of HEY 15530 with the following change. Delete the term Armed Forces and substitute "Uniformed Services" in subsections(c), (2), (4) and (5).

The unavailability of these drugs for transitioning servicemembers causes unnecessary hardship because finding the ideal medication and dose takes time, and abrupt changes for these medications are not medically advisable. Because of the potential adverse health effects that could arise if medication is not taken as intended, medication management is crucial to effective continuity of care for members transitioning out of the military. There have been numerous GAO reports documenting the adverse effects of this un-coordination between the two departments.

This bill mandates inter-departmental coordination and collaboration on the establishment of a joint transitional formulary which will be reviewed and updated frequently with periodic reports to Congress. It puts into policy what should already be happening at the Military Treat Facility-VA hospital level.

MOAA supports HEY15532.

MOAA thanks the Committee and the members who sponsored or co-sponsored the measures before us today. We look forward to the opportunity to work with the members to make these important provisions a matter of law.



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202 479 2200 or 800 809 9448
WWW.ROA.ORG

September 29, 2016

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

On behalf of ROA's members, I have attached a recently passed resolution in support of the full-practice authority of all advanced practice registered nurses, including Certified Registered Nurse Anesthetists.

Expanding the use of APRNs would address the needs of VA to provide quality care to veterans, and it could also lead to increased employment of Guard and Reserve service members who are qualified APRNs from the Army, Navy, Air Force, combat support hospitals, and forward surgical teams.

According to the Air National Guard, APRNs (specialty 46YX) will "*. . . use critical judgment to provide direct patient care. This will include providing comprehensive health assessments and differential diagnoses, as well as planning and prescribing treatments in the management of acute and chronic illness. You'll also handle health promotion and preventive care within your specialized area of practice. You may also have the opportunity to work with humanitarian outreach programs and victims of natural disaster or conflict where your skills will be desperately needed.*"

ROA believes the training and experience Guard and Reserve APRNs have will lead VA to seek out these professionals to fill vacancies across the Veterans Health Administration. Additionally, Guard and Reserve APRNs are available in AK, CA, CO, HI, IL, IN, KY, MA, MD, NH, NJ, NM, NY, OH, RI, and TX, to name a few states. This availability ensures they are not concentrated in just certain parts of the country but are available to VA from coast to coast.

Using APRNs is a positive step toward filling vacancies, increasing veteran hiring, and reducing unemployment for Guard and Reserve service members. Thank you for your consideration on this important matter.

ROA represents all the uniformed services of the United States, who would be favorably affected by your support of APRNs. Please have your staff call Susan Lukas, ROA's legislative director, at 202-646-7713 or slukas@roa.org, for any assistance.

Sincerely,

Jeffrey E. Phillips
Executive Director

"Serving Citizen Warriors Through Advocacy and Education Since 1922"

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RESERVE OFFICERS ASSOCIATION

Resolution No. 16-03

Advanced Practice Registered Nurses Full Practice Authority

WHEREAS, nearly 6,000 Advanced Practice Registered Nurses (APRN) are currently serving our Veterans in the Veterans Health Administration (VHA) to include nurse practitioners (NPs); certified registered nurse anesthetists (CRNAs) certified nurse-midwives (CNMs); and clinical nurse specialists (CNSs); and

WHEREAS, APRNs deliver primary, specialized, and community healthcare, the full range of anesthesia services and, chronic pain management; and

WHEREAS, the VHA is currently experiencing a shortage of health care providers and struggles to provide our Veterans with timely access to high quality health care; and

WHEREAS, unnecessary barriers to full practice authority deter qualified APRNs from pursuing a career in VHA hindering VA's ability to recruit and retain highly qualified APRNs; and

WHEREAS, current policy in many states and VHA facilities do not allow APRNs to practice to the top of their training and expertise as full practice authority (FPA) providers; and

WHEREAS, adopting this policy would align with recommendations of the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare (CAMH) report, *Independent Assessment of the Health Care Delivery Systems and Management Processes of the Department of Veterans Affairs* and the Institute of Medicines report, *The Future of Nursing: Leading Change, Advancing Health*; and

WHEREAS, adopting this policy would align with current APRN policy in Air Force Instruction 44-102, Navy FY14 Nursing Corps Special Pay Implementation Guidance (14Nov12), and Army Regulation 40-68, Clinical Quality Management; and

WHEREAS, the VHA is reviewing the policy to recognize the FPA of all four APRN provider types;

NOW, THEREFORE, BE IT RESOLVED, that the Reserve Officers Association of the United States, chartered by Congress, urge the Department of Veterans Affairs, a federal entity that should accept practice authority across all states commensurate with military facility authority, to employ all categories of advanced practice registered nurses to help meet the growing workforce needs of the Dept of VA and increase Veterans access to the highest quality health care they have earned and deserve.

Source: Department of Virginia, August 12, 2016

Approved by the National Convention, September 14, 2016

Congress of the United States
Washington, DC 20515

March 22, 2016

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
U.S. Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

The undersigned Members of Congress fully support the Department of Veterans Affairs moving forward with a proposal to improve our Veterans access to quality healthcare by extending Full Practice Authority (FPA) to Advanced Practice Registered Nurses (APRNs) within the Veterans Health Administration (VHA). Given the recommendation from the recently completed VHA Independent Assessment, to recognize the full practice authority of all four APRN specialties, we urge you to immediately take the necessary steps to implement this important policy so that our nations Veterans have timely access to the high quality care they have earned and deserve.

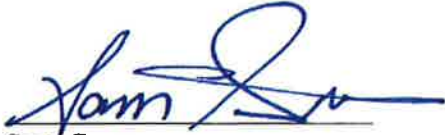
Within the healthcare assessment Section 6.4.2, Policy Options to Increase Productivity of Existing Resources, its first recommendation 6.4.2.1, is to "Formalize Full Nursing Practice Authority throughout VA." This policy would not only help address the increasing healthcare demands of our nations Veterans, but would also improve and standardize high quality healthcare delivery, improving the efficiency of our VHA system. Most importantly, recognizing APRNs as FPA providers would improve Veterans' access to the highest quality care and make optimal use of existing VHA personnel.

The idea that APRNs should practice to the top of their training and expertise has been backed by decades of research, aligns with current APRN policy in the Army, Navy, Air Force, Combat Support Hospitals, Forward Surgical Teams and Indian and Public Health Services, is consistent with the evidence based recommendations advanced by the Institute of Medicine in their report, *The Future of Nursing: Leading Change, Advancing Health*, and will allow for greater team based clinical practice. APRNs are highly skilled healthcare professionals with expertise in the diagnosis and treatment of illness and the delivery of evidence-based nursing interventions across the entire healthcare continuum. APRNs include Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMs) and Clinical Nurse Specialists (CNSs). By recognizing APRNs as Full Practice providers the VHA would make optimal use of existing personnel and help improve access. Many VHA APRNs are Veterans of the U.S. Armed Forces themselves, providing them with a unique clinical perspective.

The time is now to move forward with this long-considered recommendation to provide our nation's Veterans with timely access to critical healthcare services in the most efficient manner possible and help ensure the long term viability of the VHA. We commend you for your commitment to improving access to exceptional services within the VHA, and believe granting APRNs recognition as FPA providers is a critical step toward achieving this goal.

Thank you for your time and consideration on this important matter and we look forward to your reply.

Sincerely,



Sam Graves
Member of Congress



Janice D. Schakowsky
Member of Congress



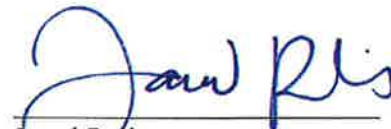
David P. Joyce
Member of Congress



David E. Price
Member of Congress



Rodney Davis
Member of Congress



Jared Polis
Member of Congress



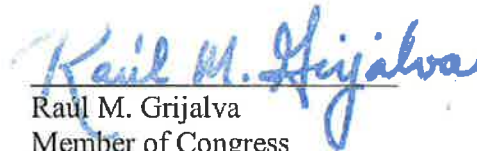
Tim Huelskamp
Member of Congress



David Loebsack
Member of Congress



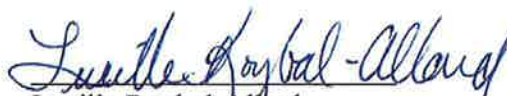
Eleanor Holmes Norton
Member of Congress



Raul M. Grijalva
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Luis V. Gutierrez
Member of Congress



Lucille Roybal-Allard
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James R. Langevin
Member of Congress

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COMMITTEE ON ENERGY AND COMMERCE

HOUSE PERMANENT SELECT
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October 2, 2014

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

I am writing to express my support for the work being done in the Veterans Administration (VA) to respond to the increasing healthcare demands of our veterans and, in keeping with that effort, to encourage prompt action to update the Veterans Health Administration's (VHA) Nursing Handbook.

America's veterans have served our nation, and they deserve timely access to high quality, safe, and efficient care. I strongly believe that allowing Advanced Practice Registered Nurses (APRNs) to practice up to their full scope of practice is part of the solution to ensuring that access. That is why I support adopting the VHA's Nursing Handbook to appropriately recognize the full practice authority (FPA) of Advanced Practice Registered Nurses (APRNs) as full practice providers (FPPs).

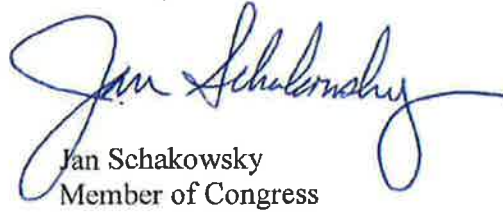
APRNs are highly-skilled practitioners with expertise in the diagnosis and treatment of illness and the delivery of evidence-based nursing interventions. APRNs include Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMs) and Clinical Nurse Specialists (CNSs). As FPPs, APRNs will provide care to the full scope of their education and skills, giving the VHA greater flexibility to utilize all providers within the healthcare team, maximize existing resources, and improving access to high quality care. Decades of research have shown that APRNs provide safe, high-quality healthcare in all settings and with all patient populations. This proposal is also consistent with the evidenced-based recommendations advanced by the Institute of Medicine in its report, *The Future of Nursing: Leading Change, Advancing Health*, and will allow for greater team-based clinical practice.

I commend you for your commitment to improving access to exceptional services within the VHA. Again, I believe granting APRNs recognition as FPPs is an important step toward achieving that goal. I urge the VA to finalize and begin implementation of the VHA's Nursing Handbook to improve healthcare for veterans throughout the country.

The Honorable Robert A. McDonald
October 2, 2014
Page 2

Thank you for your time and consideration on this important matter.

Sincerely,

A handwritten signature in blue ink, reading "Jan Schakowsky". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline that extends to the right.

Jan Schakowsky
Member of Congress

DAVID LOEBSACK
2ND DISTRICT, IOWA

COMMITTEES:
ARMED SERVICES
SUBCOMMITTEES:
MILITARY PERSONNEL
READINESS

EDUCATION AND THE WORKFORCE

SUBCOMMITTEES:
HEALTH, EMPLOYMENT, LABOR,
AND PENSIONS

HIGHER EDUCATION AND
WORKFORCE TRAINING

Congress of the United States
House of Representatives
Washington, DC 20515-1502

December 12, 2014

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The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

I am writing to express my support for the work being done in the Veterans Administration (VA) to respond to the increasing healthcare demands of our Veterans by updating the Veterans Health Administration's (VHA) Nursing Handbook.

America's Veterans have dedicated their careers to protecting our nation, and they deserve improved access to high quality, safe, and efficient care. To address this goal, adopting the VHA's Nursing Handbook to appropriately recognize the full practice authority (FPA) of Advanced Practice Registered Nurses (APRNs) as full practice providers (FPPs) will help improve Veterans access to the high quality healthcare they have earned.

APRNs are highly skilled practitioners with expertise in the diagnosis and treatment of illness and the delivery of evidence-based nursing interventions. APRNs include Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMs) and Clinical Nurse Specialists (CNSs). As FPPs, APRNs will provide care to the full scope of their education and skills giving the VHA greater flexibility to utilize all providers within the healthcare team, maximize existing resources, and in turn improve access to high quality care. Decades of research has shown that APRNs provide safe high quality healthcare in all settings and with all patient populations. This proposal is also consistent with the evidenced based recommendations advanced by the Institute of Medicine in their report, *The Future of Nursing: Leading Change, Advancing Health*, and will allow for greater team based clinical practice.

I commend you for your commitment to improving access to exceptional services within the VHA, and believe granting APRNs recognition as FPPs is an important step toward achieving this goal. I urge the VA to finalize and begin implementation of the VHA's Nursing Handbook to improve healthcare for Veterans throughout the country.

Thank you for your time and consideration on this important matter.

Sincerely,



Dave Loeb sack
Iowa's Second District

TOM COTTON
ARKANSAS

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United States Senate

November 17, 2015

COMMITTEES
ARMED SERVICES
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SPECIAL COMMITTEE ON AGING

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
U.S. Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

I am writing to express my strong support for the Department of Veterans Affairs to move forward with extending Full Practice Authority to Advanced Practice Registered Nurses.

Ensuring that our Veterans have access to quality care is a top concern of mine. The findings from the VHA Independent Assessment show that recognizing Full Practice Authority for all four APRN specialties can increase access to quality care for our Veterans. I urge you to take the necessary steps to implement this common-sense policy.

I want to raise to your attention to findings from the healthcare assessment Section 6.4.2, *Policy Options to Increase Productivity of Existing Resources*. Its first recommendation is to "Formalize Full Nursing Practice Authority throughout VA." This policy would not only help address the increasing healthcare demands of our Veterans, but would also improve and standardize high quality healthcare delivery by making optimal use of existing VHA personnel.

The idea that APRNs should practice to the top of their training and expertise has been backed by decades of research and it aligns with current APRN policy in the Army, Navy, Air Force, Combat Support Hospitals, Forward Surgical Teams and Indian and Public Health Services. APRNs include Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMs) and Clinical Nurse Specialists (CNSs). By recognizing APRNs as Full Practice providers the VHA would make optimal use of existing personnel and help improve access.

The time is now to move forward with this long-considered recommendation to provide our nation's Veterans with timely access to critical healthcare services. I strongly believe granting APRNs recognition as FPA providers is a critical step toward achieving this goal.

Thank you for your time and consideration on this important matter and I look forward to your reply.

Sincerely,



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STEERING AND POLICY

February 12, 2015

The Honorable Robert A. MacDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, D.C. 20420

Dear Secretary MacDonald:

As the Department of Veterans Affairs (VA) pursues innovative solutions to improve the quality and efficiency of the health care we provide to our nation's veterans, I write to express my support for updating the Veterans Health Administration's (VHA's) Nursing Handbook to recognize Advanced Practice Registered Nurses (APRNs) as Full Practice Providers (FPPs).

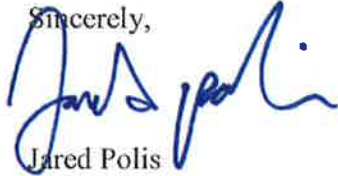
Allowing APRNs – including Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMWs), Clinical Nurse Specialists (CNSes), and Nurse Practitioners (NPs) – Full Practice Authority (FPA) within the VHA system will enable these providers to utilize the full scope of their training and expertise and help maximize the VA's ability to provide the best and most expeditious care possible to our nation's service members. Furthermore, FPA recognition for APRNs is consistent with evidence-based research demonstrating that patients are well-served when APRNs, including nurse anesthetists, are given the scope to operate as FPPs. A report by the Institute of Medicine found that limitations on APRNs' ability to operate as independent providers were "hampering the ability of APRNs to contribute to innovative health care delivery solutions" and that the "[e]limination of barriers for all professions with a focus on collaborative teamwork will maximize and improve care throughout the health care system."

The practice authority granted to APRNs who work in VHA facilities currently varies widely from state to state. Recognition of APRNs as FPPs would help establish the uniformity across states that the Institute of Medicine calls for. Moreover, it would be consistent with the model successfully applied in Colorado, where APRNs have full practice authority and play a critical role in caring for the thousands of veterans who utilize our state's VHA facilities – working both in collaboration with and independently of physicians. It is also consistent with established care models in our armed forces, in which the Army, Navy, and Air Force all allow APRNs, including nurse anesthetists, to operate to the top of their education and skills.

Thank you for your commitment to improving and modernizing the health care systems in place for our nation's service members. I encourage you to implement these proposed changes to the Nursing Handbook as quickly as possible, and I look forward to working with you to provide the

best possible health care to the men and women who have bravely risked their lives on our nation's behalf.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jared Polis", with a stylized flourish at the end.

Jared Polis
Member of Congress

REID J. RIBBLE
8TH DISTRICT, WISCONSIN

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Congress of the United States House of Representatives

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WATER RESOURCES AND ENVIRONMENT

April 13, 2016

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

I write to request full consideration of proposals to formally allow Full Practice Authority (FPA) to all qualified Advanced Practice Nurses (APN) in an effort to meet the increased healthcare needs of our Veterans.

As you may know, per the request of the Veterans Access, Choice, and Accountability Act of 2014, the RAND Corporation prepared an independent assessment for the Department of Veterans Affairs (VA) that included policy options to increase productivity of existing resources. The assessment concluded that formalizing FPA for APNs would likely be a cost effective approach to increasing productivity of the VA's existing workforce. Under FPA, APNs would have the authority to evaluate and diagnose conditions, order and interpret tests and admit patients.

A 2011 Institute of Medicine report, "The Future of Nursing: Leading Change, Advancing Health," suggests that altering the scope of practice barriers and allowing APNs to practice independently could free up physician time to handle more complex issues of other patients and increase productivity. Additionally, according to a 2015 Survey of VA Resources and Capabilities, 68 percent of respondents identified providers performing clinical activities in cases that could be performed by professionals with less training, as a key issue negatively impacting provider and system efficiency.

It is paramount that we ensure the men and women who served this country and sacrificed for our freedom are able to access healthcare professionals in a timely manner and receive the best care possible. To meet this mandate, the VA must run as effectively and efficiently as possible.

I urge the Department of Veterans Affairs to strongly consider proposals to formalize full practice authority to APNs in an effort to improve Veterans access to the highest quality healthcare they have earned and deserve.

Sincerely,

A handwritten signature in black ink, reading "Reid J. Ribble". The signature is written in a cursive, flowing style with a large initial "R".

Reid J. Ribble
Member of Congress



DAVID P. JOYCE
MEMBER OF CONGRESS
14TH DISTRICT OF OHIO

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, D.C.

COMMITTEE ON
APPROPRIATIONS

October 2, 2014

The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, D.C. 20420

Dear Secretary McDonald:

I am writing to express my support for the work being done in the Veterans Administration (VA) to adopt a Veterans Health Administration's (VHA) Nursing Handbook which recognizes the full practice authority of Advanced Practice Registered Nurses (APRNs) in response to the increasing healthcare demands of our veterans.

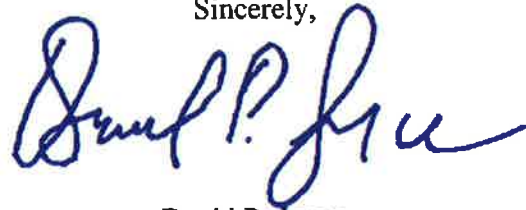
America's veterans have dedicated their careers to protecting our nation, and they deserve improved access to high quality, safe, and efficient care. Adopting the VHA's Nursing Handbook to appropriately recognize the full practice authority of APRNs as full practice providers will help improve veterans' access to the high quality healthcare they have earned.

APRNs are highly skilled practitioners with expertise in the diagnosis and treatment of illness and the delivery of evidence-based nursing interventions. APRNs include Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMs) and Clinical Nurse Specialists (CNSs). As full practice providers, APRNs will provide care commensurate with the full scope of their education and skills, giving the VHA greater flexibility to utilize all providers within the healthcare team, maximize existing resources, and, in turn, improve access to high quality care. Decades of research has shown that APRNs provide safe, high quality healthcare in all settings and with all patient populations. The proposal to recognize the full practice authority of APRNs is also consistent with the evidence-based recommendations advanced by the Institute of Medicine in its report, *The Future of Nursing: Leading Change, Advancing Health*, and will allow for greater team-based clinical practice.

I commend you for your commitment to improving access to exceptional services within the VHA, and believe granting APRNs recognition as full practice providers is an important step toward achieving this goal. I urge the VA to finalize and begin implementation of the VHA's Nursing Handbook to improve healthcare for veterans throughout the country.

Thank you for your time and consideration on this important matter. If I may be of further assistance or provide additional information, please do not hesitate to contact me at 202-225-5731.

Sincerely,

A handwritten signature in blue ink, appearing to read "David P. Joyce". The signature is fluid and cursive, with the first name "David" being the most prominent part.

David P. Joyce
Member of Congress

SAM GRAVES
6TH DISTRICT, MISSOURI

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Congress of the United States
House of Representatives

Washington, DC 20515-2506

November 18, 2014

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The Honorable Robert A. McDonald
Secretary of Veterans Affairs
Department of Veterans Affairs
801 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonald:

I am writing to express my support for the Veterans Administration (VA) updating the Veterans Health Administration's (VHA) Nursing Handbook. This work is important, given the need to respond to the increasing healthcare demands of our Veterans.


America's Veterans have dedicated their careers to protecting our nation, and they deserve improved access to high quality, safe, and efficient care. To address this goal, adopting the VHA's Nursing Handbook to appropriately recognize the full practice authority (FPA) of Advanced Practice Registered Nurses (APRNs) as full practice providers (FPPs) will help improve Veterans access to the high quality healthcare they have earned.

APRNs are highly skilled practitioners with expertise in the diagnosis and treatment of illness and the delivery of evidence-based nursing interventions. APRNs include Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), Certified Nurse Midwives (CNMs) and Clinical Nurse Specialists (CNSs). As FPPs, APRNs will provide care to the full scope of their education and skills giving the VHA greater flexibility to utilize all providers within the healthcare team, maximize existing resources, and in turn improve access to high quality care. Decades of research has shown that APRNs provide safe, high quality healthcare in all settings and with all patient populations. This proposal is also consistent with the evidence-based recommendations advanced by the Institute of Medicine in their report, *The Future of Nursing: Leading Change, Advancing Health*, and will allow for greater team based clinical practice.

I commend you for your commitment to improving access to services within the VHA, and believe granting APRNs recognition as FPPs is an important step toward achieving this goal. I urge the VA to finalize and begin implementation of the VHA's Nursing Handbook to improve healthcare for Veterans throughout the country.

Thank you for your time and consideration on this important matter.

Sincerely,



Sam Graves
Member of Congress

Certified Registered Nurse Anesthetists (CRNAs)

►► Fast Facts ◀◀

Anesthesia is 50 times safer than in the early 1980s.
(*Institute of Medicine, 1999*)

There is no difference in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.
(*Dulisse, 2010–Health Affairs*)

Nurse anesthesia care is 25 percent more cost effective than the next least costly anesthesia delivery model.
(*Hogan, 2010–Nursing Economic\$*)

Practicing in every setting, with and without anesthesiologists, CRNAs ensure patient access to healthcare and predominate in rural and other medically underserved areas.

Researchers studying anesthesia safety found no differences in care between CRNAs and anesthesiologists. (*Lewis, 2014-Cochrane Database of Systematic Reviews*)

- Nurse anesthetists have been providing anesthesia to patients in the United States for more than 150 years.
- CRNAs are advanced practice registered nurses who administer approximately **40 million anesthetics** to patients each year. More than 49,000 U.S. nurse anesthetists and student nurse anesthetists are members of the American Association of Nurse Anesthetists (AANA).
- In some states, CRNAs are the **sole anesthesia professionals in nearly 100% of rural hospitals**, ensuring patient access to obstetrical, surgical, trauma stabilization and pain management services.
- CRNAs have been **recognized Medicare Part B providers** since 1986.
- CRNAs **work in every setting in which anesthesia is delivered**, including hospitals, ambulatory surgical centers and physician offices.
- Nurse anesthesia **predominates in Veterans Hospitals and in the U.S. Armed Forces**.
- CRNA services include pre-anesthesia evaluation, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout surgery.
- **Providing acute and chronic pain management services** is within the professional scope of practice of CRNAs.



Learn more about CRNAs at
www.aana.com

AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

Office of Federal Government Affairs
25 Massachusetts Ave., NW, Suite 550
Washington, DC 20001

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Ensure Veterans Access to High Quality Care

The American Association of Nurse Anesthetists represents more than 49,000 Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists, including 900 members serving in the Veterans Health Administration (VHA). Nationwide, CRNAs deliver approximately 40 million anesthetics each year for all types of surgery and other procedures, for every type of patient, using every anesthetic technique, as well as pain care services. CRNAs have provided the majority of anesthesia to our active duty military in combat arenas since World War I and predominate in Veterans hospitals and the U.S. Armed Services.

To ensure our Veterans have access to the highest quality healthcare they have earned and deserve, on May 25th the VHA released a proposed rule to authorize Full Practice Authority (FPA) to CRNAs and other Advanced Practice Registered Nurses (APRNs). The AANA fully supports this important proposal for our Veterans.

The June 2016 report of the Commission on Care and the September 2015 Independent Assessment of the health care delivery system and management processes of the Department of Veterans Affairs, required by the Veterans Choice Access and Accountability Act of 2014, both make evidence-based recommendations to recognize the Full Practice Authority of all four APRN provider types including CRNAs. The Independent Assessment found Veterans access to surgeries is delayed by access to anesthesia services in Veterans hospitals – a problem that CRNA and APRN Full Practice Authority can help solve. Their recommendations are consistent with recommendations from the **National Academies of Medicine**¹ and they align with current APRN policy in the Army, Navy, Air Force, Combat Support Hospitals, Forward Surgical Teams and Public and Indian Health Services.

This proposal has the **official support of the Military Officers Association of America, the Air Force Sergeants Association, Iraq and Afghanistan Veterans of America, the Naval Enlisted Reserve Association, AMVETS, AARP and the American Hospital Association.**

Peer reviewed research published in the June 2016 issue of the independent, peer-reviewed scientific journal *Medical Care*, shows scope of practice (SOP) restrictions and physician supervision requirements for nurse anesthetists have no impact on anesthesia patient safety. Conducted by The Lewin Group, the study also concluded that while state physician supervision and other CRNA practice restrictions do not increase anesthesia safety, they do reduce patient access to quality care and increase costs of healthcare services.

Granting all APRNs, including CRNAs, Full Practice Authority is an evidence-based step that the VHA can take to improve Veterans access to care and to yield the efficiencies essential to the long term viability of the VHA as a health delivery system. Ignoring these recommendations in favor of the status quo delays Veterans' access to the high quality healthcare that they have earned and deserve.

Action for Congress: Contact VHA Undersecretary for Health Dr. David Shulkin to urge immediate implementation of the proposed rule, aligning VHA policy with the evidence-based recommendations from the Commission on Care's Final Report and the Independent Assessment to recognize CRNAs and other APRNs to their Full Practice Authority.



VHA Granting CRNAs Full Practice Authority Expands Veteran Patient Access to Care

As the U.S. Department of Veterans Affairs considers authorizing Advanced Practice Registered Nurses (APRNs) to provide care to their Full Practice Authority (FPA), the agency has fielded questions about the degree to which extending FPA to one APRN specialty, Certified Registered Nurse Anesthetists (CRNAs), improves Veteran access to care. The answer to this question lies in findings promulgated by the VA Independent Assessment, published literature, and observations from within the VHA, and concludes that granting FPA to CRNAs expands Veteran patient access both to procedural services and, through generating savings from eliminating unnecessary supervision arrangements, to primary and mental healthcare. FPA for APRNs is consistent with practices in the U.S. Armed Forces, the Indian Health Service, and in many facilities where Veterans access their Choice Act benefits in the commercial healthcare delivery market. It is also supported by recommendations of the Institute of Medicine and also by the Independent Assessment¹. Within the healthcare assessment, Section 6.4.2, Policy Options to Increase Productivity of Existing Resources, has as its first recommendation 6.4.2.1, Formalize Full Nursing Practice Authority throughout VA.

Where Does VHA Access to Care Arise Relating to Anesthesia Services

Veterans access to care issues are identified in numerous instances by the Independent Assessment, by observations within the VHA, and by published government reports. The Independent Assessment finds within Appendices E through I² the following examples relating to procedures requiring anesthesia:

- The paper outlines in detail feedback from healthcare administrators and professionals associated with the VHA. One noted **delay in cardiovascular surgery** delivery is because of “lack of CV anesthesia support” because “(a)nesthesia staff resistant to doing more than 1 case/day.” (p 611, 612, 613, 631, 634, 637).
- There are several expressed desires to **increase availability of out-of-OR anesthesia** (p 638, several subsequently).
- The process for **obtaining a colonoscopy is noted as especially burdensome** (p 681).

A major VHA workforce evaluation published January 2015 also reported that **CRNAs have been among the VHAs most difficult to recruit** specialties over four of the past five years³.

¹ VA Independent Assessment section on health care capabilities. Appendix B, http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities.pdf.

² VA Independent Assessment, Appendices E – I, http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities_Appendices_E-I.pdf.

³ VA Office of the Inspector General, <http://www.va.gov/oig/pubs/VAOIG-15-00430-103.pdf>.

- Educated and qualified to provide anesthesia services for cardiovascular procedures. Thus, making more efficient use of CRNA services may increase the number of cardiovascular procedures a VHA facility may provide a given community of Veteran patients.
- Commonly applied to anesthesia services in locales outside of main operating rooms, such as GI settings, cardiac catheterization facilities, and outpatient and ambulatory surgery. Thus, applying CRNA services to each of these settings may substantially improve patient flow and Veteran access to care in VAMCs offering these capabilities.
- Preferred anesthesia providers in outpatient colonoscopy facilities. Thus, assigning CRNA coverage to VHA GI units may help substantially increase the delivery of these needed services for our Veterans.

On the issues raised by additional outside observations, the findings are as follows:

- In regional anesthesia, allowing CRNAs to practice to their FPA and offer regional anesthesia in these cases, can yield a higher quality of care, safer and faster recovery times, and higher patient satisfaction.
- With respect to eliminating unnecessary supervision, the current structure duplicates staffing and increases costs. Permitting CRNAs the ability to practice to their FPA and modifying care delivery models would both ensure patient safety and result in substantial cost savings, allowing the VHA to allocate scarce resources toward other Veteran healthcare needs. Both safety and savings can be achieved where CRNAs and anesthesiologists provide anesthesia care to Veterans, conduct clinical education, ensure CRNA FPA and avoid costly double-staffing.

Recently, the Iowa City VA Medical Center has achieved promising results after moving to a CRNA Full Practice Authority anesthesia delivery model. According to a review by an Iowa City Veterans Affairs Medical Center surgeon, over the past year the acuity of patient cases increased while mortality rates decreased and morbidity ratios remained unchanged. Additionally, over the course of the year utilizing a CRNA-only anesthesia model the facility's anesthesia department labor costs per relative value unit (a measure of case complexity plus time) decreased to \$19 compared to \$24 for the Veterans Integrated Services Network (VISN) and \$68 per unit nationally. The relationship of these units to overall costs is that an average case might involve 10-15 relative value units, and an average hospital may provide thousands of cases per year.

CRNA Education and Training

Certified Registered Nurse Anesthetists (CRNAs) are highly educated, advanced practice registered nurses who deliver anesthesia to patients in exactly the same ways, for the same types of procedures and just as safely as physician anesthesiologists.



CRNAs have a minimum of **7 to 8 years** of education and training specific to nursing and anesthesiology before they are licensed to practice anesthesia.



Baccalaureate prepared RN

Minimum
1 Year

Critical care nursing experience

24 – 36
Months

Classroom and clinical
education and training



Master's or Doctoral Degree
from a COA-accredited nurse
anesthesia educational program

By 2025, all anesthesia
program graduates will
earn doctoral degrees

CRNAs obtain an average of



3.5 years

of **critical care nursing experience** before entering a nurse anesthesia program.² They are the **only** anesthesia professionals with this level of critical care experience prior to entering an educational program.

Constant Learners



CRNAs must pass a **National Certification Examination** for entry into practice and be recertified every 4 years so they are current on the latest anesthesia techniques and technologies.

They must also pass a Continued Professional Certification exam every **8 years**. Anesthesiologists are recertified every **10 years**.



Minimum **60 hours**
approved continuing
education & **40
hours** professional
development activities
every 4 years



Attest to substantial
anesthesia practice



Maintenance of current
state licensure



CRNAs are qualified to administer **every type of anesthesia in any healthcare setting**, including pain management for acute or chronic pain.



Manage difficult cases



Use advanced monitoring
equipment

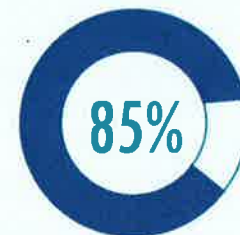


Interpret diagnostic information



Respond appropriately in any
emergency situation

Research shows
that CRNAs are



less costly to educate and
train than anesthesiologists.³

As the demand for healthcare continues to grow, increasing the number of CRNAs will be key to containing costs while maintaining quality care.

1. Council on Accreditation of Nurse Anesthesia Educational Programs

2. NBCRNA Continued Professional Certification (CPC) Handbook, 2016

3. Update of Cost Effectiveness of Anesthesia Providers, Lewin Group Publications, May 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416, 482, and 485

[HCFA-3049-F]

RIN 0938-AK08

Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services.

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Anesthesia Services Condition of Participation (CoP) for hospitals, the Surgical Services Condition of Participation for Critical Access Hospitals (CAH), and the Ambulatory Surgical Center (ASC) Conditions of Coverage Surgical Services. This final rule changes the physician supervision requirement for certified registered nurse anesthetists furnishing anesthesia services in hospitals, CAHs, and ASCs. Under this final rule, State laws will determine which professionals are permitted to administer anesthetics and the level of supervision required, recognizing a State's traditional domain in establishing professional licensure and scope-of-practice laws. States and hospitals are free to establish additional standards for professional practice and oversight as they deem necessary.

The hospital anesthesia services CoP, CAH surgical services CoP, and the conforming change to the anesthesia Conditions of Coverage apply to all Medicare and Medicaid participating hospitals, CAHs, and ASCs.

EFFECTIVE DATE: These regulations are effective on March 19, 2001.

FOR FURTHER INFORMATION CONTACT:

Stephanie A. Dyson RN, BSN (410) 786-9226

Debra M. Hattery RN, MS (410) 786-1855

SUPPLEMENTARY INFORMATION:

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This **Federal Register** document is also available from the **Federal Register** online database through GPO access, a service of the U.S. Government Printing Office. The Website address is <http://www.access.gpo.gov/nara/index.html>.

I. Background

A. Legislation

Sections 1861(e)(1) through (e)(8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Section 1820 of the Act contains criteria for application for States establishing a Critical Access Hospital. Sections 1832(a)(2)(F)(i) and 1833(i) provide coverage requirements for ASCs. Section 1861(bb) of the Act, provides definitions for certified registered nurse anesthetists (CRNAs) and their services.

B. General

On December 19, 1997, we published the proposed rule, "Hospital Conditions of Participation, Provider Agreements and Supplier Approval," (62 FR 66726) in the **Federal Register**. This proposed rule generated over 60,000 public comments and approximately one-third of these comments addressed the proposed condition eliminating the Federal requirement for physician supervision of a licensed independent practitioner permitted by the State to administer anesthetics.

In 1997, when we proposed our changes to the current hospital conditions of participation (CoPs), we stated our desire to move toward standards that are patient-centered, evidence-based, and outcome oriented. We also stated that a fundamental principle was to facilitate flexibility in how a hospital meets our performance expectations, and eliminate structure and process requirements unless there is evidence that they are predictive of desired outcomes for patients. Where there is agreement on a structure or process requirement predictive of desired patient outcomes, we included that in our proposed rule. In fact, comments on the standard for physician

supervision of CRNAs reflect a split between those who support flexibility in allowing States and hospitals to make decisions about anesthesia services and those who oppose the provision, supporting, instead, the structural requirement for physician supervision. We have already finalized the Organ Donation and Transplantation and Patients' Rights conditions, which were contained in the December 19, 1997 proposed hospital rule. We are now finalizing part of the anesthesia services standard describing anesthesia administration. We continue to work to finalize the other issues in the December 19, 1997 hospital conditions of participation proposed rule.

C. Need for Amended Anesthesia Services CoP

The existing hospital CoPs require hospitals, CAHs, and ASCs to provide quality care by adhering to our organizational and staffing requirements. The current hospital CoPs are not written in a way that promote or encourage a hospital, CAH, or ASC to assess the quality of care and improve patient outcomes. One of the clear messages we received from industry groups and professionals as we pursued this change in regulatory approach is that the old way of focusing on structure and process no longer represented current practice or the best available method to foster delivery of quality health care services.

Since publication of the December 19, 1997 proposed rule, we have continued to receive input from representatives of individual industry groups and have analyzed thousands of public comments from individual providers, beneficiaries, hospitals, and professional and provider organizations. We have given careful consideration to the scientific literature cited by commenters. We have found no compelling scientific evidence that an across-the-board Federal physician supervision requirement for CRNAs leads to better outcomes, or that there will be adverse outcomes by relying on State licensure laws instead.

We are also responding to considerable Congressional activity that has occurred since the 1997 publication of the proposed rule. Interest by Congress on both sides of the issue of physician supervision resulted in Appropriations Conference committee language in the Conference Report to the Balanced Budget Refinement Act (BBRA) of 1999 (H. Conf. Rep. No.106-

studies' failure to control adequately for possible correlations among variables such as higher risk patients and hospital characteristics (for example, size and sophistication of medical technology) as they would affect deaths attributable to anesthesia.

- There is no evidence that there would be adverse outcomes by relying on States and hospitals to regulate the appropriate supervision and scope of practice of health professionals administering anesthesia. Nor has there been any evidence that States do a poor job in regulating and overseeing health care professional practice or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

In the Silber studies, the authors did not conclude that CRNAs may be providing poor care that might more likely lead to negative outcomes. The 1992 study did not address whether there is an association between patient outcomes and the type of professional who furnished anesthesia. The anesthesia variable used in the study was not specific to the patient, rather it was a variable at the hospital level (for example, percent of anesthesiologists who are board-certified). The anesthesia variable might be a proxy indicator of quality of the hospital: Thus, there would be lower mortality in the higher quality hospitals and if a complication occurred the patient would more likely be rescued.

Silber urges "that the limitations of the project be recognized." The limitations include: There were relatively few deaths, adverse outcomes and failures, and relatively few patients per hospital so the rates could only be compared for groups of hospitals, not specific facilities.

In a subsequent article to the one summarized above, Silber and colleagues (1995) found that "most of the predictable variation in outcome rates among hospitals appears to be predicted by differing patient characteristics rather than by differing hospital characteristics, that is, by who is treated rather than by the resources available for treatment." The authors found higher proportions of board-certified anesthesiologists to be associated with lower death and failure rates, but also with higher adverse occurrence rates. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. The study did not address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians. The

article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another. Silber and his colleagues (1997) have also conducted methodological studies that compare the usefulness of three outcome measures, mortality, complication and failure-to-rescue rates.

They concluded that for the general surgical procedures studied, the complication rate is poorly correlated with the death and failure rate. The authors suggest that great caution be taken when using complication rates and that they should not be used in isolation when assessing hospital quality of care. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. Nor did the study address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians, the issue in the rule. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law.

Even on its own terms, the study has the following methodological shortcomings:

- The study used a non-experimental research design and only examined claims data, instead of reviewing medical records or observing actual care. Even though the researchers statistically controlled for 106 proxy indicators of care, without a stronger research design, they can only make a weak conclusion about an "association" between a variable and an outcome.
- The study did not control for the cause of death. Cases where a patient died from an anesthesia related cause, the surgery itself, an unrelated medical error, or an unknown medical condition are all considered, regardless of the cause of death. Not having data on deaths actually attributed to anesthesia is problematic since the mortality data used covers any death occurring within

30 days of a hospital admission. Events occurring 30 days from admission cannot be attributed to the anesthesia care alone. While the researchers argue that "delayed" death (that is, within 30 days of admission) is the appropriate measure of mortality for anesthesia care, the study does not produce causal evidence for such a theory. At a minimum, the researchers could have presented results for mortality measured for shorter periods of time such as within 72 hours of admission which may or may not have shown different outcomes for short-term and delayed deaths.

- Both the study and comparison groups included cases where physicians supervised CRNAs and personally furnished anesthesia. (The study group also included cases where anesthesiologists medically directed residents). The purpose of the study was to examine differences when an anesthesiologist versus a non-anesthesiologist physician is involved in the case. One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision.

- The study used data where anesthesia was furnished by unknown suppliers (incorrectly referred to in the article as "unknown providers") either personally providing care or supervising CRNAs. Because a supplier is not a physician there are likely to be data coding errors which could contaminate and bias the results.

Even if the methodological shortcomings were fixed, because the study did not address the issue in the final rule, it is inappropriate to impute results from this study to the issue in this final rule, the provision of care by CRNAs supervised and not supervised by physicians.

Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs. Such a policy is much more restrictive than current Medicare policy because it would prohibit non-anesthesiologist physicians to supervise CRNAs. This would make it difficult to perform surgeries in many small and rural hospitals because anesthesiologists generally do not practice in these hospitals.

Finally, even if we were to consider that the Silber article should guide our policy, we note, that due to the difference between relative risk and absolute risk, the reported size-effect is too small to cause us to change our



Major Flaws in Memtsoudis Study

Important Background Information about the National Survey of Ambulatory Surgery:

- NSAS does identify anesthesia provider, in addition to a variety of relevant patient information.

“Within sampled facilities, a sample of ambulatory surgery visits was selected using a systematic random sampling procedure. . . . Following selection of ambulatory surgery visits, data were abstracted from the medical record for each visit. The Medical Abstract Form used in data collection contained items relating to the personal characteristics of the patient, including birth date or age, sex, race, ZIP Code, but not name and address; administrative information, including the date of the surgery, and disposition of the patient; principal and other additional expected sources of payment; medical information, including diagnoses and surgical and nonsurgical procedures performed, as well as types of anesthesia administered and by whom; and information on follow-up with the patient.”

ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NSAS/NSAS2006_rev.pdf

(Pg. 10-11, Accessed April 4, 2014)

Very relevant survey for surgery and anesthesia

- There is a survey design difference in sampling based on geography between the 1996 survey and the 2006 survey.

“Unlike the 1994-1996 NSAS which used a stratified cluster design, the 2006 NSAS did not cluster facilities into geographic primary sampling units or PSUs. Facilities were stratified by facility type (hospital versus freestanding), ambulatory surgery status of hospitals (i.e. whether or not the hospital performed such surgery), facility specialty, and geographic region.”

ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NSAS/NSAS2006_rev.pdf

(pg. 10 Accessed April 4, 2014.)

Minor one

- NSAS is very explicit about addressing relative standard error and the possibility of unreliable weighted estimates if too few samples are represented in original survey.

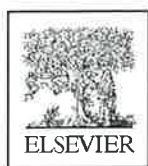
According to NSAS on 2006 report:

“The relative standard error (RSE) of an estimate is obtained by dividing the SE by the estimate itself. The RSE is expressed as a percentage of an estimate and can be multiplied by the estimate to obtain the SE. Because of low reliability, estimates with a RSE of more than 30 percent or those based on a sample of fewer than 30 records are replaced by asterisks (*). The estimates that are based on 30 to 59 patient records are preceded by an asterisk (*) to indicate that they also have low reliability”

Knowing that the CDC specifically discusses unreliable data elements in their survey indicates the greater importance of this issue.

Risk Adjusted Odds Ratio:

The NSAS survey does *collect* diagnosis (non-procedure) ICD-9 information on patients, principal source of expected payment (e.g., Medicare, Medicaid, Self-Pay, Private, Tricare, etc...), and distinguishes metropolitan statistical area. This study was published in 2011, and most know that when addressing quality and in particular comparing providers, at minimum a researcher should attempt to adjust for patient co-morbidity, age, gender, and race. That said, socio-economic and geographic factors are also becoming widely accepted as confounding variables. Unfortunately, regarding patient specific factors, this study's adjusted odds was for age and gender, and did not acknowledge race, co-morbidity, insurance status, and metropolitan statistical area. This too is a major methodological flaw.



Answering the call to address chronic pain in military service members and veterans: Progress in improving pain care and restoring health

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ABSTRACT

Chronic noncancer pain (CNCP) in military and veteran populations mirrors the experience of chronic pain in America; however, these two populations have unique characteristics and comorbid conditions such as traumatic brain injuries, postconcussive syndrome, posttraumatic stress disorder, and behavioral health disorders that complicate the diagnosis and treatment of chronic pain. Military members and veterans may also be stigmatized about their conditions and experience problems with integration back into healthy lifestyles and society as a whole following deployments and after military service. The military and veteran health care systems have made chronic pain a priority and have made substantial strides in addressing this condition through advances in practice, education, research, and health policy. Despite this progress, significant challenges remain in responding to the wide-spread problem of chronic pain. The purpose of this article is to: (a) examine the state of CNCP in military and veteran populations; (b) discuss progress made in pain practice, education, research, and health policy; and (c) examine research, evidence-based practice guidelines, and expert consensus reports that are foundational to advancing pain care and improving health for military service members and veterans with CNCP. In addition, recommendations are proposed to address this widespread health problem through the expanded use of advanced practice registered nurses, the implementation of models of care, and use of national resources to educate health care providers, support practice, and promote effective pain care.

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Table 1 – Evidence for the Occurrence of Pain in Service Members and Veterans

Author (Date)	Objective	Sample Size	Prevalence and Incidence of Pain	Level of Evidence*
Clark et al., 2009	Compare the physical and emotional presentations and pain treatment outcomes of service members who sustained polytrauma secondary to combat blast (CB) with those of service members with combat injuries involving no blast (CNB) or individuals injured in noncombat (NC) settings	128 service members	Participants with moderately severe to severe pain (NRS >7) per study group: CB (37.2%), CNB (29.4%), NC (30.2%)	3
Edlund et al., 2014	Characterize the dosing and duration of opioid therapy for patients with chronic noncancer pain (CNCP) in the VHA	VHA patients with CNCP annually Fiscal year 2009: 1,332,810 Fiscal year 2010: 1,405,563 Fiscal year 2011: 1,437,392	Most common CNCP among veterans were arthritis pain (65.1%), back pain (42.1%), and neuropathic pain (13.5%)	4
Higgins et al., 2014	Examine variations in demographics and prevalence of mental health conditions between OEF/OIF/OND veterans with persistent pain and no pain	5,242 OEF/OIF/OND veterans	73% of those in the total sample reported experiencing persistent pain (NRS ≥4) with a mean NRS of 6.4 (out of 10)	4
Lew et al., 2009	Studies the prevalence of symptoms consistent with chronic pain, PTSD, and persistent postconcussive symptoms (PPCS) among OEF/OIF veterans	340 OIF/OEF veterans	81.5% of sample reported chronic pain; 42.1% of the veterans were diagnosed with all three conditions simultaneously	4
Outcalt et al., 2014	Assess the physical, functional, and psychological experience of veterans with comorbid chronic pain and PTSD	241 OEF/OIF veterans with diagnosed chronic pain	PTSD group (28% of sample) experienced greater pain severity, more pain-related disability, greater pain interference, more pain catastrophizing, lower pain self-efficacy, higher pain centrality, than the no PTSD group	3
Pugh et al., 2014	Identify comorbidity clusters among diagnoses of deployment specific (traumatic brain injury, PTSD, pain) and chronic conditions, and to examine the association of these clusters with health care utilization and adverse outcomes	191,797 OEF/OIF veterans who received care in the VA between 2008 and 2010	Pain diagnoses, including chronic pain, were predominant in three of the six identified cohorts comprising 18.8% of the total sample	4

Note. NRS, numeric rating scale; OEF, Operation Enduring Freedom; OIF, Operation Iraqi Freedom; OND, Operation New Dawn; PTSD, posttraumatic stress disorder.

* Level of evidence determined using rating system for the hierarchy of evidence (Melnyk & Fineout-Overholt, 2011). The hierarchy is a seven-tier scale, with the best evidence receiving the strongest rating. The strongest evidence to base clinical practice on is rated level 1 and includes both systematic reviews and meta-analyses of randomized controlled trials or evidenced-based clinical practice guidelines based on systematic reviews of randomized controlled trials. Level 2 comprises evidence from well-designed randomized control trials, Level 3 evidence is produced by controlled trials with no randomization, and level 4 contains cohort and case-control research studies. Level 5 evidence is produced from systematic reviews of descriptive and qualitative studies, level 6 includes both single descriptive studies or qualitative work, and the weakest evidence, level 7, is limited to expert opinions.

within the peripheral and central nervous system, and this results in abnormal pain processes including sustained pain hypersensitivity (Latremoliere &

Woolf, 2009). This abnormal state is not only responsible for the transition of acute to chronic pain but explains why many patients continue to

pain and communicating this information in their settings and across transitions in care (Pain Management Task Force, 2010). To respond to these challenges, the PMTF designed a new pain scale, the Defense and Veterans Pain Rating Scale (DVPRS). The DVPRS uses a numeric rating scale (NRS) enhanced with functional word descriptors at each pain level,

“traffic light” color coded bars to delineate levels of pain (mild 1–4, green; moderate 5–6, yellow; and severe 7–10, red) and facial depictions of pain (Figure 1). Four supplemental questions screen for how much pain interferences with usual activity and sleep, and how pain affects mood and contributes to stress (Figure 1).

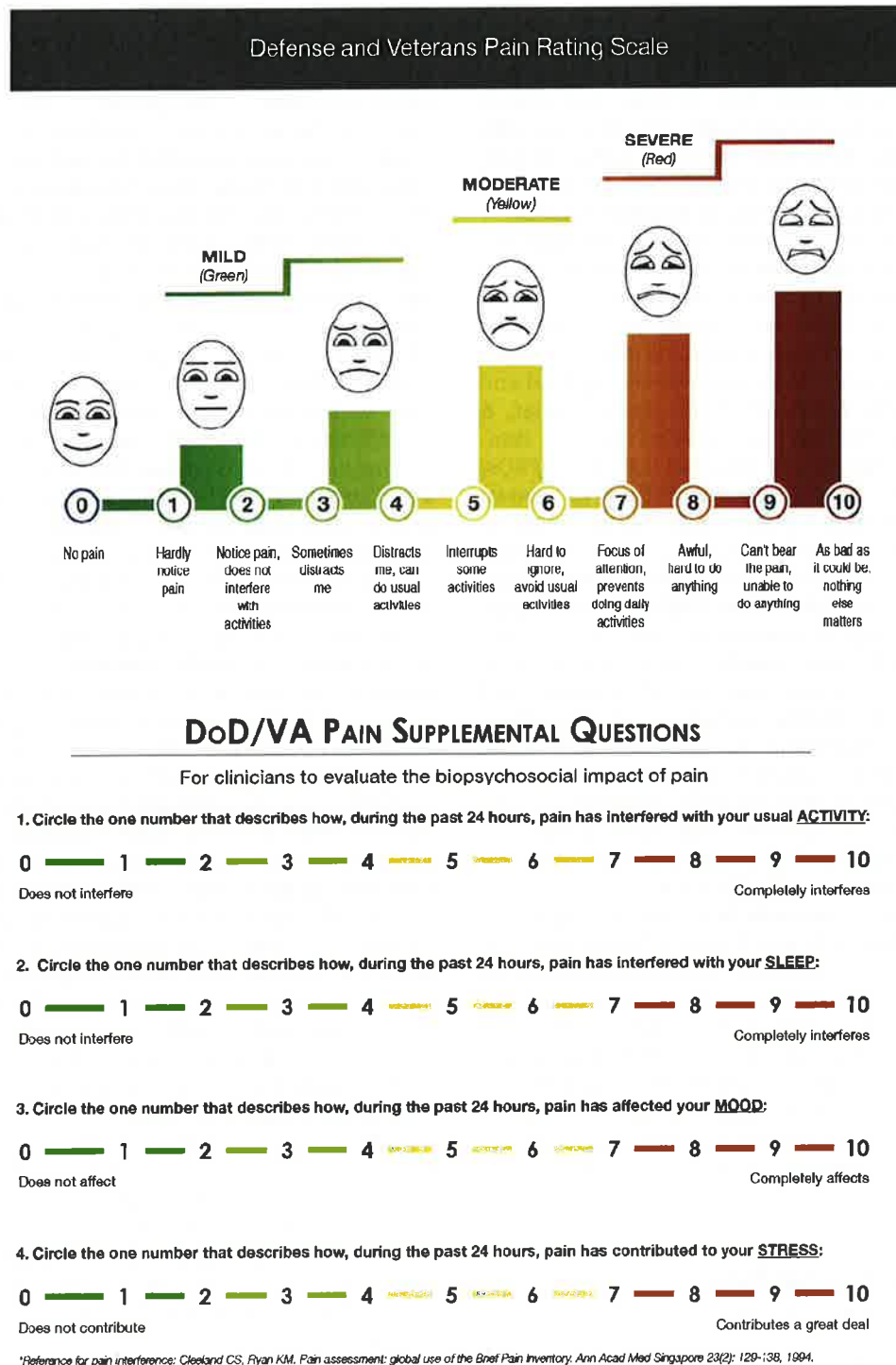


Figure 1 – Defense and veterans pain rating scale.

Table 2 – Evidence for Intervention-Based Studies of Pain

Author (Date)	Type of Article	Objective	Sample Size	Interventions for Pain	Relevant Findings	Level of Evidence*
Bair et al., 2015	RCT	Determine whether a stepped-care intervention is more effective than usual care in reducing pain-related disability, pain interference, and pain severity	241 veterans	12 weeks of analgesic therapy optimization according to an algorithm coupled with pain self-management strategies followed by 12 weeks of CBT	A statistically significant decrease in pain disability, interference, and severity was seen among those receiving the intervention compared to the controls receiving usual care demonstrating the effectiveness of interventions	2
Berry et al., 2014	RCT	Determine the effectiveness of heart rate variability coherence biofeedback (HRVCB) as a pain and stress intervention	14 veterans	A self-regulation technique, quick coherence, coupled with computer-based HRVCB	Treatment group demonstrated improved HRV coherence, lower pain severity scores, lower levels of stress, and fewer physical activity limitations compared to control group	2
Boldt et al., 2014	Systematic review	Appraise evidence on the effects of nonpharmacological interventions for the treatment of chronic neuropathic and nociceptive pain for spinal cord injury	616 participants across 16 RCT studies	Electrical brain stimulation, repetitive transcranial magnetic stimulation, exercise programs, acupuncture, self-hypnosis, transcutaneous electrical nerve stimulation, CBT	Few serious or long-lasting effects demonstrated from all included interventions for managing pain among spinal cord injury patients	1
Chiesa & Serretti, 2011	Systematic review	Review of controlled studies investigating the efficacy of mindfulness-based interventions (MBI) for reducing pain and improving depressive symptoms	951 participants across 10 studies	MBI	Limited and insufficient evidence that MBIs are effective in reducing pain and improving depressive symptoms	2
Crawford, Lee, May, and Active Self-Care Therapies for Pain (PACT) Working Group, 2014	Systematic review	Review the full range of active self-care patient-centered complementary and integrative medicine	1,087 participants across 10 RCT studies	Acupressure, self-correcting exercises, transcutaneous electric nerve stimulation	Reduction in chronic pain across all three interventions was demonstrated but no recommendation	2

(continued on next page)

Table 2 – (Continued)

Author (Date)	Type of Article	Objective	Sample Size	Interventions for Pain	Relevant Findings	Level of Evidence*
Matthias, Miech, Myers, Sargent, & Bair, 2012	Qualitative	Ascertain perceptions among participants who completed a multicomponent intervention for OEF/OIF/OND veterans with chronic musculoskeletal pain	26 veterans	Analgesic management, pain self-management instruction, and brief CBT	conditions, such as work disability Patients in both the control and intervention groups reported that nurses facilitated their self-management by helping patients find what works for their pain, holding patients accountable for their pain management and motivating them and providing emotional support	3
Matthias et al., 2015	Pre-post study	Pilot test, a peer support intervention, involving peer delivery of pain self-management strategies, for veterans with chronic musculoskeletal pain	Nine veteran peer coaches and 17 veteran patients	Peer coaches attended a 3-hour training session co-led by the a psychologist and nurse and after training, each peer coach was assigned two patients to “coach” and support for 4 months	Patients with chronic musculoskeletal pain who were paired with a peer coach for 4 months improved on all self-efficacy, pain centrality, and patient activation measures	3
McGeary et al., 2012	Cohort study	Identify cost benefit for functional restoration treatment of chronic musculoskeletal pain as a function of posttreatment changes in costly medical intervention utilization	66 active duty military personnel	Functional occupational restoration treatment	Participants receiving the intervention had significantly fewer procedures including emergency department intervention, injections, and radio frequency nerve ablation compared to participants receiving usual care	3
Watson et al., 2014	Pre-post study	Asses patient satisfaction with a “Pain Education School” program using a mixed-methods approach	219 veterans	12 week program to learn pain relief and prevention, understand pharmacologic and nonpharmacologic interventions, and	Patients reported the program as helpful, informative, and would recommend to others; participant reported cognitive skills as the most	3

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Table 3 – State-of-the-Science and Consensus Recommendations Related to Pain

Author (Number of Pages)	Title/Organization(s)	Type of Document	Major Recommendations/ Number of Recommendation Categories	Recommendation Highlights Relevant to Military and Veteran Care
American Association of Nurse Anesthetists, 2014 (7 pages)	Chronic pain management guidelines American Association of Nurse Anesthetists	Expert consensus	<p>(1) CRNAs practice in accordance with their professional scope of practice, federal and state law, and facility policy</p> <p>(2) Patient evaluation, management, imaging technology, documentation, communication, and continuous quality improvement</p> <p>Number of major recommendation categories: 6</p>	<ul style="list-style-type: none"> States that CRNAs are integral to care of patients with drug seeking behaviors Advises that CRNAs should develop a pain management treatment agreement with the patient, when applicable Instructs clinicians to monitor, measure, and evaluate pain, functionality, and response to the treatment plan so as to modify treatment plan accordingly Urges providers to document pertinent information on the patient's medical record in an accurate, complete, legible, and timely manner Recommends imaging technology as appropriate to enhance patient safety and improve accuracy of pain management
Chou, et al., 2009a (40 pages)	Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain American Pain Society and American Academy of Pain Medicine	Evidence-based guideline	<p>(1) Guidance on patient selection and risk stratification and informed consent for opioid therapy</p> <p>(2) Monitoring for opioid side effects and adverse events</p> <p>(3) Use of cointerventions</p> <p>(4) Identify a medical home and when to obtain consultation</p> <p>Number of major recommendation categories: 14</p>	<ul style="list-style-type: none"> Encourages the use of psychological therapy States that cognitive behavioral therapy is consistently demonstrated to be effective for CNCP (strong recommendation, moderate-quality evidence) Recommends the patient receive coordinated interprofessional care with access to clinicians who provide comprehensive care (strong recommendation, moderate-quality evidence) Advises that opioid selection, initial dosing, and titration be modified according to the patient's health status, opioids naivety, therapeutic goals, and

(continued on next page)

Table 3 – (Continued)

Author (Number of Pages)	Title/Organization(s)	Type of Document	Major Recommendations/ Number of Recommendation Categories	Recommendation Highlights Relevant to Military and Veteran Care
Chapman et al., 2010 (23 pages)	Opioid pharmacotherapy for chronic noncancer pain in the United States: A research guideline for developing an evidence-base Expert Panel	Expert consensus	<p>Number of major recommendation categories: 8</p> <ul style="list-style-type: none"> • (1) Improvements to research strategy to study the effectiveness of long-term opioid pharmacotherapy • (2) Improvements in evidence-generation methodology • (3) Potential research topics for generating new evidence <p>Number of major recommendation categories: 4</p> <ul style="list-style-type: none"> • (1) When to initiate or continue opioids for chronic pain • (2) Opioid selection, dosage, duration, follow-up, and discontinuation • (3) Assessing risk and addressing harms of opioid use <p>Number of major recommendation categories: 12</p> <ul style="list-style-type: none"> • Encourages frequent monitoring for patients prescribed methadone for chronic pain and have a history of substance abuse, an unstable social environment, and those with comorbid psychiatric conditions • Provides recommendations on how to enhance participation for opioid research • Recommends the use of the VA database, which contains a vast amount of longitudinal information, on opioid pharmacotherapy in CNCP patients and it merits for research • Encourages the use of large databases for routine care and resource sharing via internet • Recommends that opioids should not be considered first line or routine therapy for chronic pain due to limited benefits • Advises providers to establish treatment goals with all patients before starting opioid therapy for chronic pain • Encourages the utilization of multimodal analgesia • Demonstrates that insufficient evidence exists to determine how harmful effects of opioids differ depending on patient demographics or patient comorbidities 	include discussion of risks, moderate average benefits, and treatment alternatives guide patient decisions regarding surgery for persistent pain
Dowell et al., 2015 (56 pages)	CDC guidelines for prescribing opioids for chronic pain United States, 2016 Centers for Disease Control and Prevention	Evidence-based guideline		

(continued on next page)

Table 3 – (Continued)

Author (Number of Pages)	Title/Organization(s)	Type of Document	Major Recommendations/ Number of Recommendation Categories	Recommendation Highlights Relevant to Military and Veteran Care
Management of Chronic Multisymptom Illness Guideline Working Group, 2014 (9 pages)	VA/DoD clinical practice guideline for the management of chronic multisymptom illness Available at: www.AHRQ.gov	Evidenced-based guideline	<ul style="list-style-type: none"> (1) Acupuncture as part of the management of patients with pain-predominant symptoms of chronic multisymptom illness (CMI) (2) Nonsteroidal antiinflammatory drugs (NSAID) for treating certain peripheral pain symptoms associated with CMI, although these do not necessarily lead to beneficial effects (3) Tramadol for treating certain pain symptoms associated with CMI that fail to respond to other nonopioid analgesic medications or non-pharmacologic approaches (4) Serotonin-norepinephrine reuptake inhibitor (SNRI) for the treatment of patients with clinical symptoms of pain-predominant CMI (5) Tricyclic antidepressants, selective serotonin reuptake inhibitor (SSRI), and/or pregabalin for the treatment of patients with clinical symptoms of pain-predominant CMI 	treatment groups for low back pain was small (acupuncture vs. placebo; mobilization vs. physical therapy), medium (acupuncture vs. no treatment; massage vs. relaxation), or large (acupuncture vs. manipulation, in favor of manipulation; massage vs. physical therapy) Suggests the use of multimodal therapies in patients with pain-predominant symptoms of CMI Recommends pharmacological and nonpharmacological therapies for patients with clinical pain symptoms

Number of major recommendation categories: 5

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Table 3 – (Continued)

Author (Number of Pages)	Title/Organization(s)	Type of Document	Major Recommendations/ Number of Recommendation Categories	Recommendation Highlights Relevant to Military and Veteran Care
			(4) Synchronize a culture of pain awareness, education, and proactive intervention Number of major recommendation categories: 4	as the musculoskeletal action plan for chronic pain patients

Note. CDC, Centers for Disease Control; CNCP, chronic noncancer pain; CRNAs, Certified Registered Nurse Anesthetists; DoD, Department of Defense; VA, Veterans Affairs.

Working Group, 2010). Universal precautions for risk-deterrent approaches should be implemented for all patients with CNCP receiving long-term opioid analgesics and tailored to risk stratification criteria (Webster, Brennan, Kwong, Levandowski, & Gudin, 2016). Risks for opioid misuse, abuse, and addiction are certainly higher in patients with an active substance abuse problem, history of prescription opioid abuse, and previously exhibiting aberrant behaviors, whereas lower risk would be defined by no history of substance abuse and minimal, if any, risk factors (Webster & Fine, 2010).

New Health Policy: Strategic Plan for Pain

The National Pain Strategy developed by the Inter-agency Pain Research Coordinating Committee (IPRCC) and released in early 2016 provides a comprehensive population health-level plan (National Pain Strategy: A Comprehensive Population Health-Level Strategy for Pain, 2016). The IPRCC was established by the National Institute of Health (NIH) to advance pain research, care, and education in response to the 2010 Patient Protection and Affordable Care Act. The national strategic initiatives outlined in this plan are aligned with the core recommendations from IOM's report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (2011) and promotes tangible objectives and targeted plans for pain care. Federal stakeholders in this plan include the DoD and VHA. Strategies focus on professional training, public education and communication, service delivery and reimbursement, prevention and care, disparities in pain management and access to care, and population studies. This report will have important implications for the adoption of universal and standard approaches to addressing pain as a major health problem. The plan includes a strategic focus on interprofessional pain education to achieve defined competencies in the delivery of pain care.

Nursing and Interprofessional Pain Education

The National Defense Authorization Act of 2010 mandated the development and implementation of targeted efforts to address the crisis of pain treatment in military and veteran populations. This legislation drew attention to the inadequacy of formal education in chronic pain management in nursing and medical schools. Experts have called for the need to systematically integrate pain content into curriculum, conduct competency-based evaluations of learning, utilize interprofessional and interactive learning, and better prepare faculty teaching pain content as solutions to improving pain education and training (Arwood et al.,

Table 4 – Recommendations for Call for Actions**Supporting Research, Evidence-based Practice Guidelines, and Expert Consensus Reports, Policy Reports, and Other Resources****Practice**

(1) APRNs practicing in military health care and VHA systems should practice to the fullest extent of the law and within their scope of practice. For CRNAs, this includes the delivery of regional anesthesia and ketamine as an analgesic in both United States and during deployment settings.

(2) Clinical care for chronic pain treatment must be aligned with evidence-based guidelines, expert consensus reports, clinical practice resources (algorithms), and current research.

(3) Nurses should access and utilize resources from the Defense and Veterans Center for Integrative Pain Management (DVCIPM) and VHA Pain Management websites to support practice.

(4) APRNs should design, implement, and lead collaborative pain care models that integrate pharmacological, complementary and alternative, and behavioral and cognitive therapies.*

(5) Patient-reported outcomes (PROs) for pain screening and assessment at military health care and VHA facilities should incorporate the Defense and Veterans Pain Rating Scale (DVPRS), and if available, the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) measures.

Education

(6) Educational online resources on the National Institutes of Health (NIH) Pain Consortium, VHA Pain Management, and DVCIPM (Joint Pain Education Project—JPEP) should be integrated into nursing undergraduate and graduate curriculum. Students, clinical nurses, APRNs, nurse leaders, and nurse educators should utilize these educational resources for independent-guided learning and continuing education in pain management.

(7) Academic institutions should engage in the American Association of Colleges of Nursing (AACN) Joining Forces Initiative, and incorporate, track, and report content related to military and veteran health. Requirements should be established for the number of hours and/or credits devoted to pain content.

(8) Nursing undergraduate and graduate programs should include interprofessional pain education and training as part of their curriculum.

(9) Nursing faculty teaching pain content should be educated in current pain assessment and management practices.

(10) Military service members, veterans, and their families should be directed to patient education materials and resources for understanding pain and its treatment and strategies for self-management of pain.

(11) Evidence-based pain guidelines and expert consensus reports should be widely disseminated to all health care professionals managing patients with pain.

Research

(12) The DoD and Department of Veterans Affairs should increase funding for nurse scientists to investigate the biological basis of chronic pain and outcome-based research in the treatment of chronic pain.

IOM Report: The Future of Nursing, 2011
American Association of Nurse Anesthetists, 2014
Conover & Richards, 2015

National Pain Strategy, 2016
Chapman et al., 2010
Chou et al., 2009a
Dowell et al., 2015
Management of Opioid Therapy for Chronic Pain Working Group, 2010

Pain Management Task Force, 2010
DVCIPM resources, available at: www.dvcipm.org/clinical-resources
VHA Pain Management, available at: VHA Pain <http://www.va.gov/painmanagement>

Pain Management Task Force, 2010
Office of the Secretary of Defense, 2015

NIH resources available at: http://painconsortium.nih.gov/NIH_Pain_Programs/CoEPES.html
DVCIPM resources, available at: www.dvcipm.org/clinical-resources

American Association of Colleges of Nursing Joining Forces: Enhancing Veterans' Care Tool Kit, available at: <http://www.aacn.nche.edu/joining-forces>

Pain Management Task Force, 2010
IOM Report: Relieving Pain in America, 2011
Centers for Disease Control, 2015
IOM Report: Relieving Pain in America, 2011
American Association of Colleges of Nursing, 2014

Bair et al., 2015
Matthias et al., 2012
Watson et al., 2014

See Table 3
Katzman et al., 2014

Gereau et al., 2014

(continued on next page)

general, within the VHA systems. These authors propose numerous potential solutions to overcoming challenges in engaging interprofessional learners, evaluating learning, and measuring patient experiences and outcomes. They also advocate for substantial changes in policy and the health care culture to support interprofessional education, and the need to advance team-based models of care to realize the benefits of this type of education on provider and patient outcomes.

Pain Educators

A requisite for successfully preparing students and clinicians to care for patients with chronic pain is to have qualified faculty to teach pain content. The American Society of Pain Educators (ASPE) is a multidisciplinary organization that joins health care professionals to share "best practices" for pain education to inform its membership. This organization disseminates resources and promotes dialog among clinicians from multiple disciplines and practice areas and educators to address critical pain curriculum. ASPE has instituted a certification examination for pain educators, and the Certified Pain Educator Program sets eligibility criteria and competencies for pain educators that are universal across all disciplines to foster an interdisciplinary peer approach to pain management. Faculty and clinician educators should take advantage of this program and the multiple interprofessional instructional resources available for pain education.

Military and Veteran Health Systems Models for Pain Care

Several nurse driven and interdisciplinary models of care in military and VHA facilities demonstrate how structured and goal-oriented pain care can lead to optimal patient outcomes. For example, a randomized trial of an interdisciplinary functional restoration (FR) program for active duty military service members with chronic musculoskeletal pain was conducted at Wilford Hall Medical Center and Brooke Army Medical Center, San Antonio, Texas. Nurse supervision of FR interventions in collaboration with a physician team resulted in significant improvements in self-reported pain, disability, functional status, and fitness for military duty compared to service members receiving standard treatment in an Anesthesia Pain Clinic (Gatchel et al., 2009).

For veterans, Wiedemer, Harden, Arndt, and Gallagher (2007) instituted a nurse practitioner (NP)-directed Opioid Renewal Clinic at the Philadelphia Veterans Affairs Medical Center to support PCPs in managing patients with CNCP at risk for substance abuse through PCP training, NP and pharmacist oversight of an evidence-based opioid prescribing algorithm, patient counseling, and stringent opioid abuse

and misuse detection measures. Of the 171 (51% of 335 enrolled in the program) who initially exhibited opioid-related aberrant behaviors, 77 (45%) successfully maintained adherence to opioid regimens and reduced their aberrant behaviors. The Evaluation of Stepped Care for Chronic Pain Program measured the efficacy of nurse care manager interventions in a randomized clinical trial with 241 Iraq and Afghanistan veterans with chronic musculoskeletal pain exposed to a stepped-care intervention program or usual care (Bair et al., 2015). The intervention consisted of 12 weeks of optimization of analgesic therapy followed by 12 weeks of instructional self-management strategies and brief cognitive behavioral therapy. Statistically significant reductions in pain-related disability, pain interference, and pain severity were observed in the intervention group compared to the usual care group (Bair et al., 2015).

On a larger scale, the VHA has developed its own system of integrated pain care using a Stepped Care Model of Pain Management (SCM-PM), which employs an evidence-based framework to promote guideline-concordant care. The SCM-PM starts with pain care delivered by PCPs, followed by secondary care with consultation in pain medicine clinics that includes interventional, rehabilitation and behavioral therapy, and finally, referral to tertiary interdisciplinary pain centers (Murphy, Clark, Dubyak, Sanders, & Brock, 2012; Rosenberger, Philip, Lee, & Kerns, 2011). Progression to higher level pain care is based on the complexity of pain issues, conditions refractory to standard treatments, risks for substance abuse and addiction, and the need for more integrative care from pain specialists. Key elements of this model include: pain assessment and treatment, evaluation of outcomes and quality of pain management, clinician competence and expertise in pain management, research, and coordination of a national VHA pain management strategy. Frontline nurses in primary care are integral to the success of this model by delivering and coordinating pain care. A qualitative study of nurses' experiences and perceptions with the VHA SCM-PM care model revealed positive impressions with patient-centered and team-based care; however, nurses expressed challenges related to the pervasive and time consuming demands around managing patients receiving opioid therapy and navigating systems barriers, e.g., insufficient options for alternative therapies, staff shortages, and lack of patient education materials (Pellico, Gilliam, Lee, & Kerns, 2014).

Within the VHA, patient-centered medical homes are emerging for diagnosis- and population-specific care. The concept of "pain medical home" and integrated care models within military health and VHA systems has tremendous potential to drive patient-centered chronic pain care with its focus on team-based care and holistic approaches in coordinating chronic pain treatment that integrate pharmacological, cognitive and behavioral, complementary and alternative, and physical therapies. Cheatle, Kloczek, and

used in austere battlefield environments to minimize the effects of traumatic pain (Plunkett, Turabi, & Wilkinson, 2012).

To prepare nursing pain specialists, it will be important for the DoD to offer and fund pain fellowships to train military nurses in the management of chronic pain. For instance, congressional language in the National Defense Authorization Act could contain provisions for support of military APRNs to complete accredited fellowship programs in chronic pain. This would expand a more qualified nursing workforce, NPs and CRNAs, and build a pipeline of a broad base of practitioners who could assume responsibilities for the management of pain in both acute and primary care settings.

Clearly, there is a compelling need to support nurse scientists in the military health care and VHA systems to conduct pain research and to increase research budgets to fund this research. Despite the significant prevalence of chronic pain across civilian, military, and veteran populations, federal agencies, including the DoD and VHA, allocate only a very small percentage of their annual research budgets to pain research (Gereau et al., 2014; Office of Pain Policy NINDS, 2012). As recently as 2012, only \$21 million of the DoD budget and only \$13.4 million of the Department of Veterans Affairs budget was spent on funding pain research. In contrast, the NIH, the largest funder of pain research, earmarked \$396 million dollars to pain research which in turn equates to only about \$4 spent to advance current understanding and science of pain research per individual living with chronic pain; the lowest amount per living person distributed across persons with major health conditions (Office of Pain Policy NINDS, 2012).

Above all, APRNs must be allowed to practice within the full scope of the law or federal regulation as recommended by the report by the Institute of Medicine, 2011 "The Future of Nursing: Leading Change, Advancing Health" (Committee on the Robert Wood Johnson Foundation Initiative on the Future of Nursing, at the Institute of Medicine, 2011). A comprehensive report from Duke University outlines the economic benefits of less restrictive practice for APRNs on economic benefits to health care expenditures, quality of health care, and local growth of the economy. An analysis of various studies indicates that expanded use of APRNs under less restrictive practice regulations can potentially translate into health system savings ranging from 0.63 percent to 6.2 percent (Conover & Richards, 2015). In a systematic review, Newhouse et al. (2011) examined 37 studies for NP and certified midwives practices finding a high level of evidence to support equivalent levels of patient satisfaction, self-reported health status, and functional status outcomes, and mortality rates. These authors were unable to find studies for CRNAs that met criteria for inclusion, and no studies specifically captured outcomes for chronic pain. As such, there is a compelling need to demonstrate the cost benefit and quality outcomes for APRN delivered pain care.

The military health system has made strides in addressing barriers to APRNs' extent of practice, and the VHA has opportunities to maximize the scope of practice for APRNs by updating their regulations for APRN practice. Currently, the VHA is proposing new regulations for APRN practice, including the four recognized roles of clinical nurse specialists, NPs, certified nurse midwives, and CRNAs, that grant full practice authority (Frontlines to Lifelines Act of 2015). This proposed rule would affect over 6,000 APRNs (Veterans Access to Quality Healthcare Alliance, n.d.) including more than 4,000 NPs (American Academy of Nurse Practitioners, 2015) and over 900 CRNAs (data from the AANA) employed within the VHA, and increase access to primary and specialty care for veterans, including veterans suffering from chronic pain. In addition, veterans would have more choices in selecting the type of providers to manage their chronic pain conditions and potentially reduce VHA financial expenditures for quality pain care. The VHA would also be better positioned to recruit health professionals leaving or retiring from the military health system. Just like the portability of patient electronic health records between the two systems, the ability to transfer credentialing and privileging requirements would substantially improve efficiencies in onboarding military health professions into the VHA system. Many military APRNs have a passion to serve this patient population and look for opportunities to continue to care for military members and veterans through employment within the VHA after separating or retiring from the military.

Conclusions

In summary, preparing and empowering qualified health care professionals across all transitions in military and veterans care and strengthening health systems to deliver comprehensive chronic pain care require both a nursing and interprofessional coordinated effort. **Clearly, more nursing pain specialists are needed to not only implement aggressive acute pain care to prevent chronic pain but also to effectively treat chronic pain with evidence-based integrative therapies that include multimodal analgesia, interventional techniques, and complementary and alternative approaches to pain management.** Nurses should continue to develop, lead, and test interventions for CNCP and existing and new models of pain care that achieve greater efficiency in access to care and patient encounters and better quality care outcomes.

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Scope of Practice Laws and Anesthesia Complications

No Measurable Impact of Certified Registered Nurse Anesthetist Expanded Scope of Practice on Anesthesia-related Complications

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Background: Scope of practice (SOP) laws governing Certified Registered Nurse Anesthetists (CRNAs) vary by state and drive CRNA practice and reimbursement.

Objective: To test whether the odds of an anesthesia complication vary by SOP and delivery model (CRNA only, anesthesiologist only, or mixed anesthesiologist and CRNAs team).

Methods: Anesthesia claims and related complications were identified in a large commercial payor database, including inpatient and ambulatory settings. Logit regression models were estimated by setting to determine the impact of SOP and delivery model on the odds of an anesthesia-related complication, while controlling for patient characteristics, patient comorbidities, procedure and procedure complexity, and local area economic factors.

Results: Overall, 8 in every 10,000 anesthesia-related procedures had a complication. However, complications were 4 times more likely in the inpatient setting (20 per 10,000) than the outpatient setting (4 per 10,000). In both settings, the odds of a complication were found to differ significantly with patient characteristics, patient comorbidities, and the procedures being administered. The odds of an anesthesia-related complication are particularly high for procedures related to childbirth. However, complication odds were not found to differ by SOP or delivery model.

Conclusions: Our research results suggest that there is strong evidence of differences in the likelihood of anesthesia complications by patient characteristics, patient comorbidities, and the procedures

being administered, but virtually no evidence that the odds of a complication differ by SOP or delivery model.

Key Words: scope of practice, anesthesia complications, anesthesia delivery model, CRNA, anesthesiologist

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BACKGROUND

Advance Practice Registered Nurses (APRNs) are an important resource to the health care system; however, barriers to full APRN practice limit the full utilization of the APRN workforce.^{1,2} According to the 2008 APRN Consensus Model, APRN professional activities are overseen by state nursing boards, which determine their legal scope of practice (SOP).³ Both the APRN Consensus Model and the Institute of Medicine expressed the value of APRNs being able to practice to the full extent of their training.^{3,4}

Both Certified Registered Nurse Anesthetists (CRNAs) and anesthesiologists are trained to provide the full range of anesthesia-related care. CRNAs face barriers similar to other APRNs, and state SOP restrictions play a crucial role in how anesthesia is delivered.

The issue regarding CRNA SOP entails restrictive language specifying the extent of physician involvement in the delivery of anesthesia. A restrictive SOP for CRNAs is a scope containing a requirement for physician involvement (at facility level or in the state law). Examples of such restrictions include supervision, immediate presence, timely onsite consultation, and physically present and available on the premises. A nonrestrictive SOP is a scope containing no or minimal requirements for physician involvement. In this case, minimal involvement may come in the form of requirements for collaboration and/or direction.

The rationale for CRNA SOP restrictions often focuses on years of training and anesthesia quality outcomes. Several studies have compared anesthesia-related complications or mortality by anesthesia delivery model.^{5–9} These studies explored the implications of anesthesia provider type on inpatient outcomes in subsets of the population, including Medicare beneficiaries or women of child-bearing age. With 1 exception,⁹ the current literature suggests no difference in quality based on anesthesia provider type.^{5–8} Nevertheless, many states still maintain restrictive CRNA SOP.

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TABLE 1. Summary Statistics for Optum Data

Variables	Inpatient (N = 1,467,348)		Outpatient (N = 4,273,122)	
	Mean	SD	Mean	SD
Complication	0.002	0.044	0.0004	0.021
Age 0–4	0.011	0.102	0.027	0.163
Age 5–14	0.016	0.124	0.034	0.181
Age 15–24	0.057	0.231	0.046	0.210
Age 25–34	0.198	0.398	0.069	0.253
Age 35–44	0.128	0.334	0.115	0.319
Age 45–54	0.113	0.316	0.189	0.391
Age 55–64	0.155	0.362	0.215	0.411
Age 65–74	0.158	0.364	0.179	0.383
Age 75–84	0.117	0.321	0.102	0.302
Age 85+	0.049	0.216	0.0246	0.155
Female	0.660	0.474	0.567	0.495
CRNA only	0.130	0.336	0.247	0.431
AA only	0.558	0.497	0.478	0.500
Medical direction 1:1	0.050	0.217	0.033	0.180
Medical direction 1:2–4	0.259	0.438	0.239	0.426
Supervision 1:1 > 4	0.004	0.060	0.002	0.048
Direction/collaboration	0.363	0.481	0.306	0.461
Supervision	0.394	0.489	0.436	0.496
Arrhythmia	0.234	0.424	0.126	0.332
Aortic stenosis	0.056	0.231	0.027	0.161
Diabetes	0.222	0.415	0.183	0.387
Cancer	0.256	0.436	0.249	0.433
Hypertension	0.502	0.500	0.464	0.499
COPD	0.226	0.418	0.179	0.383
Rural indicator	0.052	0.222	0.065	0.247
Base units	6.668	3.293	4.723	1.222
Percent below poverty	15.941	5.041	15.712	5.069
Median family income (in “000s”)	67.680	16.058	68.101	17.182

Data on percent in poverty and median family income at the 3-digit zip code level were obtained from the American Community Survey and are available at <https://www.census.gov/programs-surveys/acs/data/summary-file.2012.html>.

TABLE 2. Classification of Scope of Practice State Laws or Regulations by Setting

No Supervision or Direction		Direction/Collaboration in Nursing Statute or Hospital Rules		Supervision in Either Nursing or Hospital Statute, State Rules or Hospital Rules, or Both	
		Inpatient and ER	Ambulatory	Inpatient and ER	Ambulatory
Alaska	Alaska	Arizona	Arizona	Alabama	Alabama
California	California	Connecticut	Connecticut	Arkansas	Arkansas
Colorado	Colorado	Delaware			Delaware
Hawaii			District of Columbia	District of Columbia	
Idaho	Idaho	Georgia	Georgia	Florida	Florida
Iowa	Iowa	Illinois	Illinois		Hawaii
Kansas	Kansas	Indiana			Indiana
Montana	Montana	Kentucky	Kentucky	Louisiana	Louisiana
New Hampshire	New Hampshire	Maryland	Maryland	Maine	Maine
New Mexico	New Mexico	Massachusetts	Massachusetts	Michigan	Michigan
North Dakota	North Dakota	Mississippi			Mississippi
Oregon	Oregon	Minnesota	Minnesota	Missouri	Missouri
Tennessee	Tennessee	Nebraska	Nebraska	New Jersey	New Jersey
Texas	Texas	Nevada	Nevada	New York	New York
Vermont	Vermont	North Carolina	North Carolina	Ohio	Ohio
Washington	Washington	Pennsylvania	Pennsylvania	Oklahoma	Oklahoma
		South Dakota	South Dakota	Pennsylvania	
		Wisconsin	Wisconsin	Rhode Island	Rhode Island
				South Carolina	South Carolina
				Utah	Utah
				Virginia	Virginia
				West Virginia	West Virginia
				Wyoming	

TABLE 3. Top 60 Inpatient and Outpatient Procedures for All Delivery Models

Rank	Inpatient				Outpatient			
	CPT Description	CPT Code	%	Cumulative %	CPT Description	CPT Code	%	Cumulative %
1	Anal, vag delivery	01967	0.156	0.156	Low intestine scope	00810	0.195	0.195
2	Surg lower abdomen	00840	0.071	0.227	Upper GI visualize	00740	0.101	0.296
3	Surg upper abdomen	00790	0.068	0.295	Lens surgery	00142	0.100	0.396
4	Cs delivery	01961	0.068	0.363	Knee joint surgery	01400	0.040	0.436
5	Knee arthroplasty	01402	0.057	0.420	Surg lower abdomen	00840	0.030	0.467
6	Upper GI visualize	00740	0.052	0.472	Skin, ext/per/atruunk	00400	0.028	0.495
7	Spine, cord surgery	00670	0.037	0.509	Lower arm surgery	01810	0.026	0.521
8	Hip arthroplasty	01214	0.029	0.539	lower leg bone surg	01480	0.026	0.547
9	Anal, cs deliv add-on	01968	0.024	0.562	N block/inj, prone	01992	0.026	0.573
10	Skin, ext/per/atruunk	00400	0.022	0.584	Procedure on mouth	00170	0.025	0.598
11	Low intestine scope	00810	0.021	0.605	Surg upper abdomen	00790	0.024	0.622
12	Spine, cord surgery	00630	0.016	0.622	Hysteroscope/graph	00952	0.021	0.643
13	Surgery of femur	01230	0.015	0.636	Surgery of shoulder	01630	0.020	0.663
14	Lower leg bone surg	01480	0.015	0.651	Head/neck/ptrunk	00300	0.018	0.681
15	Neck organ, l and over	00320	0.013	0.664	Nose/sinus surgery	00160	0.017	0.698
16	Bladder surgery	00910	0.012	0.676	Bladder surgery	00910	0.017	0.715
17	Hrt surg w/pmp ag > 1	00562	0.011	0.687	Repair of hernia	00830	0.013	0.728
18	CAT or MRI scan	01922	0.010	0.697	Anorectal surgery	00902	0.012	0.739
19	Hip joint surgery	01210	0.010	0.707	Tympanotomy	00126	0.012	0.751
20	CABG w/pump	00567	0.010	0.717	Lower arm surgery	01830	0.011	0.762
21	Cranial surg nos	00210	0.009	0.725	procedures on eye	00140	0.010	0.772
22	Head/neck/ptrunk	00300	0.008	0.733	Neck organ, l and over	00320	0.010	0.782
23	Neck vessel surgery	00350	0.008	0.741	Vaginal procedures	00940	0.009	0.791
24	Surgery for obesity	00797	0.008	0.749	CAT or MRI scan	01922	0.009	0.799
25	l lung ventilation	00541	0.008	0.757	Perc img tx sp proc	01936	0.008	0.808
26	Vaginal hysterectomy	00944	0.008	0.764	Kidney stone destruc	00873	0.008	0.816
27	Kidney/ureter surg	00862	0.008	0.772	Spine, cord surgery	00630	0.008	0.824
28	Removal of prostate	00865	0.007	0.779	Vitreoretinal surg	00145	0.008	0.832
29	Electroshock	00104	0.007	0.786	Surgery of breast	00402	0.006	0.839
30	Cardiac electrophys	00537	0.006	0.792	Blepharoplasty	00103	0.006	0.845
31	Vascular access	00532	0.006	0.799	Genitalia surgery	00920	0.006	0.851
32	Thigh arteries surg	01270	0.006	0.805	Lower leg surgery	01470	0.006	0.858
33	Knee joint surgery	01400	0.006	0.810	Inc/missed ab proc	01965	0.006	0.864
34	Chest procedure	00520	0.006	0.816	vascular access	00532	0.006	0.870
35	Surgery of abdomen	00860	0.005	0.821	Stone removal	00918	0.006	0.876
36	Tx interv rad hrt/cran	01926	0.005	0.826	Surgery of shoulder	01610	0.006	0.882
37	Stone removal	00918	0.005	0.831	Surgery of abdomen	00860	0.005	0.887
38	Shoulder replacement	01638	0.005	0.835	Electroshock	00104	0.005	0.893
39	Surgery of breast	00402	0.004	0.840	ear surgery	00120	0.005	0.898
40	Anorectal surgery	00902	0.004	0.844	Repair of hernia	00750	0.004	0.902
41	Surgery of shoulder	01630	0.004	0.848	Bladder tumor surg	00912	0.004	0.906
42	Spine, cord surgery	00600	0.004	0.852	Removal of prostate	00914	0.004	0.910
43	Pacemaker insertion	00530	0.004	0.856	Spine, cord surgery	00670	0.003	0.913
44	Revise hip repair	01215	0.004	0.860	Repair of hernia	00752	0.003	0.916
45	Removal of prostate	00914	0.004	0.864	Cardiac electrophys	00537	0.003	0.919
46	Correct heart rhythm	00410	0.004	0.867	Elbow area surgery	01710	0.003	0.922
47	Lower arm surgery	01830	0.004	0.871	Correct heart rhythm	00410	0.003	0.925
48	Lower leg surgery	01470	0.003	0.875	Vascular shunt surg	01844	0.003	0.928
49	Procedure on mouth	00170	0.003	0.878	Lower arm procedure	01820	0.003	0.931
50	Repair of hernia	00752	0.003	0.881	Vag hysterectomy	00944	0.003	0.933
51	Heart surg w/o pump	00560	0.003	0.884	chest procedure	00520	0.003	0.936
52	Vascular shunt surg	01844	0.003	0.887	Tubal ligation	00851	0.003	0.939
53	Vaginal procedures	00940	0.003	0.889	Nerve block/inj	01991	0.003	0.941
54	Intrern nerve	00220	0.003	0.892	Upper arm surgery	01740	0.002	0.943
55	Chest surgery	00540	0.003	0.895	Repair of hernia	00832	0.002	0.945
56	Surgery of shoulder	01610	0.003	0.897	Perc img dx sp proc	01935	0.002	0.947
57	Knee area surgery	01392	0.003	0.900	Ther interven rad, vei	01930	0.002	0.949
58	CABG w/o pump	00566	0.003	0.903	Kidney/ureter surg	00862	0.002	0.950
59	Perc img tx sp proc	01936	0.002	0.905	Knee arthroplasty	01402	0.002	0.952
60	Repair of hernia	00830	0.002	0.907	Surgery of breast	00404	0.002	0.954

has no statistically detectable impact on complications. To avoid potential bias in the estimation of SEs due to unobservable factors that may be correlated across observations, SEs are clustered at the state level. Hypotheses

involving single coefficients are tested by z tests. ORs were determined to be significant with a P -value at the 0.10 level or lower. Joint tests involving multiple coefficients are tested by χ^2 tests with degrees of freedom equal to the number of

delivery add-on has an OR of 3.219. Lower intestine scope is relatively safe—its OR estimate equals 0.445 in the inpatient setting and 0.576 in the outpatient setting; both estimates are statistically significant at the 0.05 level.

Another potential control for the risk of an anesthesia-related complication is the BUs for the procedure, which measure procedure complexity. The estimates in Table 4 do not indicate any relationship of BUs with risk of an anesthesia-related complication in either setting. The BU control is highly insignificant in both the inpatient setting where on average we see relatively higher BU procedures and the outpatient setting. The results indicate that the procedure controls are much better predictors of procedure risk than the BUs associated with the procedure.

The hypothesis that anesthesia-related complications do not differ with patient characteristics can be rejected for both settings (χ^2 P -value=0). Examining the individual coefficients related to age, all but one of the inpatient model ORs associated with age are insignificant and none of the outpatient model age effects are individually significant. In the outpatient model, females are estimated to be 20% more likely than males to experience a complication in that setting (OR=1.198, P -value=0). The inpatient model difference due to sex is less, 13% (significant at the 0.1 level). Generally speaking, the evidence indicates that once other factors are controlled for, there is some variation in the risk of an anesthesia-related complication by patient age group and sex. However, measured by ORs, the variation does not seem to be large.

Although there is strong evidence of differences in anesthesia complications by patient comorbidities and the undergone procedure, and some evidence of variation with patient characteristics, the results in Table 4 provide virtually no evidence that complications differ by either SOP classification or by delivery model. The joint hypothesis tests involving the SOP coefficients and the delivery models are highly insignificant.

Considering first the SOP estimates found in Table 4, most of the ORs are <1.0 when compared with the reference indicator (no supervision). However, none of the estimated ORs is individually statistically significant at the P -value <0.1 level in any of the settings. Specifically, results did not indicate statistical significance in any setting for the supervision categories (OR_{inpatient} = 1.046, OR_{outpatient} = 0.864) and direction/collaboration categories (OR_{inpatient} = 0.972, OR_{outpatient} = 0.753). Finally, the P -values for the joint tests involving the SOP indicators are both quite high. Therefore, we fail to reject the hypothesis that anesthesia-related complications are unrelated to SOP classification.

Similarly, none of the delivery model ORs is individually statistically significant at P -value <0.05. The OR estimates for CRNA-only are 1.149 and 1.009 for the inpatient and outpatient settings, respectively. However, neither estimate is significant at the P -value <0.10. These results indicate that the hypothesis that the risk of anesthesia-related complications is the same whether anesthesia is delivered by a CRNA acting alone or by an anesthesiologist acting alone cannot be rejected. Furthermore, the joint test P -values of 0.700 (inpatient) and 0.472 (outpatient) indicate that the joint

hypothesis that anesthesia-related complications do not vary by delivery model cannot be rejected for either setting.

Of the geographic controls included in our models, only the rural indicator is statistically significant for the inpatient setting; however, only approximately 6% of procedures were in rural areas. Inpatient procedures performed in rural areas have about 1.213 times higher (P -value=0.04) likelihood of complications than procedures performed in urban areas. No difference was found in the outpatient setting. We find no evidence that complications vary with the poverty rate (OR_{inpatient} = 1.003, OR_{outpatient} = 0.994). Local area median family income was associated with a significantly lower likelihood of anesthesia complications for the outpatient setting (OR=0.990, P -value=0.10), but no difference was found for the inpatient setting.

DISCUSSION

The primary finding of this study is that there is no statistically significant difference in the risk of anesthesia complications based on the degree of restrictions placed on CRNAs by state SOP laws. Nor is there evidence that the risk of complications varies by delivery model. This evidence suggests that there is no empirical evidence for SOP laws that restrict CRNAs from practicing at levels that are below their education and training based on differences in anesthesia complication risk.

There is strong evidence of differences in anesthesia complications by patient characteristics, patient comorbidities, and the procedures for which anesthesia was administered. Depending on setting, we also find some evidence of variation with geographic factors.

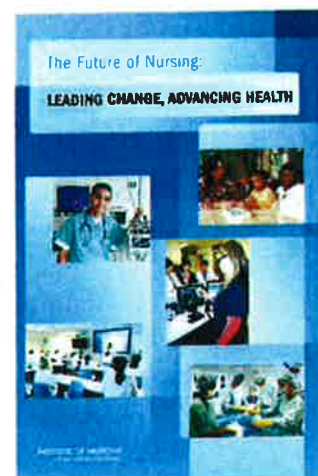
In addition to being consistent with the previous literature, our findings are based on a very large commercial payor database that encompasses a wider patient population and includes data from both the inpatient and ambulatory settings. The larger sample sizes associated with this database provide a greater probability of detecting differences in complications across delivery models and state SOP categories, if differences exist.

An unavoidable limitation of this study is the possibility that small differences in risk may exist but cannot be detected even with the relatively large sample sizes of this study. Moreover, these findings are based on a privately insured population. We have no reason to believe the results would differ for other populations, but publicly insured and uninsured populations are underrepresented here. Finally, though we have controlled for a large number of factors affecting the underlying risk of anesthesia, including the procedure; the age, sex, and comorbidities of the patient; and whether the hospital or outpatient setting was in an urban or rural location, there remains a possibility that selectivity based on factors for which we do not control could have affected the results.

To the extent that state SOP limitations on CRNAs are based on the assumption that anesthesia provided by CRNAs acting alone is riskier than other delivery models, the evidence presented in this study should be considered. Potentially unnecessary restrictions can reduce patient access to

The Future of Nursing

Leading Change, Advancing Health



With more than 3 million members, the nursing profession is the largest segment of the nation's health care workforce. Working on the front lines of patient care, nurses can play a vital role in helping realize the objectives set forth in the 2010 Affordable Care Act, legislation that represents the broadest health care overhaul since the 1965 creation of the Medicare and Medicaid programs. A number of barriers prevent nurses from being able to respond effectively to rapidly changing health care settings and an evolving health care system. These barriers need to be overcome to ensure that nurses are well-positioned to lead change and advance health.

In 2008, The Robert Wood Johnson Foundation (RWJF) and the Institute of Medicine (IOM) launched a two-year initiative to respond to the need to assess and transform the nursing profession. The IOM appointed the Committee on the RWJF Initiative on the Future of Nursing, at the IOM, with the purpose of producing a report that would make recommendations for an action-oriented blueprint for the future of nursing.

Nurses practice in many settings, including hospitals, schools, homes, retail health clinics, long-term care facilities, battlefields, and community and public health centers. They have varying levels of education and competencies—from licensed practical nurses, who greatly contribute to direct patient care in nursing homes, to nurse scientists, who research and evaluate more effective ways of caring for patients and promoting health. The committee considered nurses across roles, settings, and education levels in its effort to envision the future of the profession. Through its deliberations, the committee developed four key messages that structure the recommendations presented in this report:

A number of barriers prevent nurses from being able to respond effectively to rapidly changing health care settings and an evolving health care system. These barriers need to be overcome to ensure that nurses are well-positioned to lead change and advance health.

1) Nurses should practice to the full extent of their education and training.

While most nurses are registered nurses (RNs), more than a quarter million nurses are advanced practice registered nurses (APRNs), who have master's or doctoral degrees and pass national certification exams. Nurse practitioners, clinical nurse specialists, nurse anesthetists, and nurse midwives all are licensed as APRNs.

Because licensing and practice rules vary across states, the regulations regarding scope-of-practice—which defines the activities that a qualified nurse may perform—have varying effects on different types of nurses in different parts of the country. For example, while some states have regulations that allow nurse practitioners to see patients and prescribe medications without a physician's supervision, a majority of states do not. Consequently, the tasks nurse practitioners are allowed to perform are determined not by their education and training but by the unique state laws under which they work.

The report offers recommendations for a variety of stakeholders—from state legislators to the Centers for Medicare & Medicaid Services to the Congress—to ensure that nurses can practice to the full extent of their education and training. The federal government is particularly well suited to promote reform of states' scope-of-practice laws by sharing and providing incentives for the adoption of best practices. One sub-recommendation is directed to the Federal Trade Commission, which has long targeted anti-competitive conduct in the health care market, including restrictions on the business practices of health care providers, as well as policies that could act as a barrier to entry for new competitors in the market.

High turnover rates among new nurses underscore the importance of transition-to-practice residency programs, which help manage the transition from nursing school to practice and help new graduates further develop the skills

needed to deliver safe, quality care. While nurse residency programs sometimes are supported in hospitals and large health systems, they focus primarily on acute care. However, residency programs need to be developed and evaluated in community settings.

2) Nurses should achieve higher levels of education and training through an improved education system that promotes seamless academic progression.

To ensure the delivery of safe, patient-centered care across settings, the nursing education system must be improved. Patient needs have become more complicated, and nurses need to attain requisite competencies to deliver high-quality care. These competencies include leadership, health policy, system improvement, research and evidence-based practice, and teamwork and collaboration, as well as competency in specific content areas including community and public health and geriatrics. Nurses also are being called upon to fill expanding roles and to master technological tools and information management systems while collaborating and coordinating care across teams of health professionals.

Nurses must achieve higher levels of education and training to respond to these increasing demands. Education should include opportunities for seamless transition into higher degree programs—from licensed practical nurse (LPN)/licensed vocational nurse (LVN) diplomas; to the associate's (ADN) and bachelor's (BSN) degrees; to master's, PhD, and doctor of nursing practice (DNP) degrees. Nurses also should be educated with physicians and other health professionals both as students and throughout their careers in lifelong learning opportunities. And to improve the quality of patient care, a greater emphasis must be placed on making the nursing workforce more diverse, particularly in the areas of gender and race/ethnicity.

To ensure the delivery of safe, patient-centered care across settings, the nursing education system must be improved. Patient needs have become more complicated, and nurses need to attain requisite competencies to deliver high-quality care.

3) Nurses should be full partners, with physicians and other health care professionals, in redesigning health care in the United States.

Efforts to cultivate and promote leaders within the nursing profession—from the front lines of care to the boardroom—will prepare nurses with the skills needed to help improve health care and advance their profession. As leaders, nurses must act as full partners in redesign efforts, be accountable for their own contributions to delivering high-quality care, and work collaboratively with leaders from other health professions.

Being a full partner involves taking responsibility for identifying problems and areas of system waste, devising and implementing improvement plans, tracking improvement over time, and making necessary adjustments to realize established goals. In the health policy arena, nurses should participate in, and sometimes lead, decision making and be engaged in health care reform-related implementation efforts. Nurses also should serve actively on advisory boards on which policy decisions are made to advance health systems and improve patient care.

In order to ensure that nurses are ready to assume leadership roles, nursing education programs need to embed leadership-related competencies throughout. In addition, leadership development and mentoring programs need to be made

available for nurses at all levels, and a culture that promotes and values leadership needs to be fostered. All nurses must take responsibility for their personal and professional growth by developing leadership competencies and exercising these competencies across all care settings.

4) Effective workforce planning and policy making require better data collection and an improved information infrastructure.

Planning for fundamental, wide-ranging changes in the education and deployment of the nursing workforce will require comprehensive data on the numbers and types of health professionals—including nurses—currently available and required to meet future needs. Once an improved infrastructure for collecting and analyzing workforce data is in place, systematic assessment and projection of workforce requirements by role, skill mix, region, and demographics will be needed to inform changes in nursing practice and education.

The 2010 Affordable Care Act mandates the creation of both a National Health Care Workforce Commission to help gauge the demand for health care workers and a National Center for Workforce Analysis to support workforce data collection and analysis. These programs should place a priority on systematic monitoring of the supply of health care workers across professions, review of the data and methods needed to develop

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accurate predictions of workforce needs, and coordination of the collection of data on the health care workforce at the state and regional levels. All data collected must be timely and publicly accessible.

Conclusion

The United States has the opportunity to transform its health care system, and nurses can and should play a fundamental role in this transformation. However, the power to improve the current regulatory, business, and organizational conditions does not rest solely with nurses; government, businesses, health care organizations, professional associations, and the insurance industry all must play a role.

The recommendations presented in this report are directed to individual policy makers; national, state, and local government leaders; payers; and health care researchers, executives, and professionals—including nurses and others—as well as to larger groups such as licensing bodies, educational institutions, philanthropic organizations, and consumer advocacy organizations. Working together, these many diverse parties can help ensure that the health care system provides seamless, affordable, quality care that is accessible to all and leads to improved health.

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by Brian Dulisse and Jerry Cromwell

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ABSTRACT In 2001 the Centers for Medicare and Medicaid Services (CMS) allowed states to opt out of the requirement for reimbursement that a surgeon or anesthesiologist oversee the provision of anesthesia by certified registered nurse anesthetists. By 2005, fourteen states had exercised this option. An analysis of Medicare data for 1999–2005 finds no evidence that opting out of the oversight requirement resulted in increased inpatient deaths or complications. Based on our findings, we recommend that CMS allow certified registered nurse anesthetists in every state to work without the supervision of a surgeon or anesthesiologist.

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Surgical anesthesia in the United States is administered by both anesthesiologists and certified registered nurse anesthetists (CRNAs). For almost 150 years, these nurses were the dominant providers of anesthesia services, but by 1986 the rapid influx of physicians into the specialty resulted in a greater number of anesthesiologists who practiced alone or in a team arrangement with nurse anesthetists.^{1,2} Even so, 37,000 certified registered nurse anesthetists provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals.³

Background On The Issue

Until recently, the Centers for Medicare and Medicaid Services (CMS) reimbursement rules for anesthesia providers prohibited payments to certified registered nurse anesthetists who administered anesthesia in the absence of physician supervision. This supervision could be provided by either an anesthesiologist or the surgeon,⁴ although surgeons now largely defer to anesthetists at the operating table during the administration of anesthesia and immediately after surgery.

In December 1997, CMS published a proposed rule to, in the words of the final version, “let State law determine which professionals would be permitted to administer anesthetics, and the level of supervision required for practitioners [seeing Medicare patients] in each category.”⁵ The agency later reported basing its decision on a “lack of evidence to support...[the] requirement for [surgeon or anesthesiologist] supervision of Certified Registered Nurse Anesthetists.”⁶

It should be noted that except for the extra training that anesthesiologists receive in medical school and residency in specialties other than the direct provision of anesthesia, both certified registered nurse anesthetists and anesthesiologists undergo similar classroom and clinical training in anesthesia care.⁷

Anesthesiologists opposed the proposed rule, arguing that they provide anesthesia care superior to that of certified registered nurse anesthetists,^{2,8} even though adverse events related to anesthesia are rare regardless of the provider.^{5,9–11} The final CMS rule of November 2001 maintained physician supervision of nurse anesthetists “unless the governor of a State, in consultation with the State’s Boards of Medicine & Nursing, exercises the option of exemption from this requirement” through a written request

signed by the governor.⁶

As of 1998, eighteen states permitted certified registered nurse anesthetists to practice independently of any physician,¹² although for reimbursement purposes, Medicare still required physician supervision at least by the surgeon if not by an anesthesiologist.⁶ By 2005, fourteen governors in mostly rural states¹³ had submitted written requests to Medicare and opted out of the supervised anesthesia requirement. Solo practice by certified registered nurse anesthetists is especially important in rural areas, where anesthesiologists are in short supply.

This article explores whether the change in CMS policy toward anesthesia supervision had a negative impact on patient outcomes. We begin by examining the absolute level and time trends of adverse patient outcomes within the states that opted out and those that did not.

It is important to note, however, that differences in these gross measures do not constitute *prima facie* evidence of a response to the policy change. The act of opting out of the supervision requirement does not necessarily imply any changes in the actual practice of anesthesia within any hospital in a state. The opt-out exemption does not mandate that hospitals allow certified registered nurse anesthetists to provide anesthesia without supervision by a surgeon or an anesthesiologist. It means only that Medicare would not require such supervision as a condition of reimbursement.

Nonetheless, if patient outcomes are unchanged after a state has opted out, as we show to be the case, then the requirement that governors petition CMS to exempt certified registered nurse anesthetists from physician supervision is unnecessary and should be rescinded.

Study Data And Methods

For the opt-out policy to affect outcomes, two conditions must be fulfilled. First, the opt-out policy must result in a shift in anesthesia arrangements. If the policy change does not affect anesthesia arrangements, then it alone could not affect patient outcomes.

Second, there must be some systematic difference in the outcomes associated with the different anesthetist arrangements. If the outcomes across the different arrangements are the same, then even if the policy change affected anesthesia arrangements, it would not affect overall patient outcomes in opt-out states.

We therefore examined whether there was a material change in the provision of anesthesia services away from anesthesiologists in favor of certified registered nurse anesthetists and, separately, whether there is evidence of different

outcomes associated with the two types of anesthetists. In examining outcomes, we first determined whether case-mix complexity differed between opt-out and non-opt-out states and by anesthetist training.

DATA SOURCE To address the research questions, we used the 5 percent Medicare Inpatient (Part A) and Carrier (Part B) Medicare limited data set files for 1999–2005. The files include all Part A claims from facilities and Part B claims from physicians and suppliers for a 5 percent sample of beneficiaries.

Given the distribution of states opting out of physician supervision at different times, we used seven calendar years of Medicare 5 percent data. This gives three full years of post-opt-out data for six of fourteen opt-out states and at least two full years of data for eleven opt-out states. Any deleterious effects of shifts to more anesthesia by unsupervised nurse anesthetists should be seen soon after a state opts out because more anesthesia complications would occur during the patient's inpatient hospital stay.

We abstracted Part A claims for each study year for all admissions in all Medicare surgical diagnosis-related groups (DRGs), which were 98,000–114,000 claims per year. Procedures taking place in ambulatory surgery centers were excluded because of uncertainty in measuring mortality or complications in those cases.

Because the 5 percent limited data sets do not contain the patient's measurement on the physical status scale of the American Society of Anesthesiologists, we merged onto the claims the anesthesia base units for the most complex anesthesia procedure (*International Classification of Diseases*, Ninth Revision, or ICD-9) code for each admission. For example, the base unit for a thyroid biopsy is 3; for cardiac catheterization, 8; and for tracheobronchial reconstruction, 18.¹⁴

We used the two Part B procedure modifier fields to identify three anesthesia provider arrangements: anesthesiologists practicing solo, certified registered nurse anesthetists practicing solo, and team anesthesia in which anesthesiologists supervise or direct nurse anesthetists. If a modifier on either a nurse anesthetist or an anesthesiologist claim indicated supervision or direction of the nurse anesthetist, then the anesthesia category was defined as team anesthesia.

Any nonteam hospitalization with a certified registered nurse anesthetist claim but no anesthesiologist claim was coded as certified registered nurse anesthetist solo. Finally, any procedure with an anesthesiologist claim not already characterized as team or certified registered nurse anesthetist solo was considered anesthesiologist solo.

Because all date fields in the data are aggre-

gated to the quarter level, it was not possible to accurately link inpatient Part B anesthesia claims to specific hospitalizations for patients who had multiple hospitalizations in the same quarter. Therefore, we excluded patients with more than one hospitalization in a quarter.

The resulting seven-year pooled file contained 741,518 surgical discharges. Roughly one-third did not have any anesthetist claim. The majority of cases without anesthesia bills were for procedures that often do not require an anesthetist, such as percutaneous transluminal coronary angioplasty, pacemaker lead inserts, sigmoidoscopies, bronchoscopies, diagnostic catheterizations, and endoscopic surgeries.

Hospitalizations without a Part B anesthesia claim were excluded unless a surgical procedure took place in a Medicare "pass-through" hospital. In these hospitals, claims for services by nurse anesthetists are rolled into ("passed through") the Part A hospital claims. Therefore, observations from these hospitals were assigned to the certified registered nurse anesthetist solo category.

Hospitalization claims were also deleted if a Part B inpatient anesthetist claim was present in the previous quarter for the same beneficiary with no admission claim in that quarter. We assumed in those cases that the anesthetist filed his or her claim earlier than the hospital's claim for the same admission.

This left us with 481,440 hospitalizations for analysis, of which 412,696 were in non-opt-out states and 68,744 were in opt-out states. Of the latter, 41,868 hospitalizations occurred before the state had opted out.

ANALYTIC METHODS We analyzed two outcomes measures: inpatient mortality and complications. Mortality is reported on the Medicare discharge abstract. To measure possible anesthesia complications, we identified seven relevant patient safety indicators developed by the Agency for Healthcare Research and Quality:¹⁵ complications of anesthesia (patient safety indicator 1); death in low-mortality diagnoses (indicator 2); failure to rescue from a complication of an underlying illness or medical care (indicator 4); iatrogenic pneumothorax, or collapsed lung (indicator 6); postoperative physiologic and metabolic derangements, or physical or chemical imbalances in the body (indicator 10); postoperative respiratory failure (indicator 11); and transfusion reaction (indicator 16). (Descriptions of each complication are provided in the online Appendix.)¹⁶

Each of these complications occurred only infrequently. Therefore, we used a single no/yes indicator (0 for no, 1 for yes) to show if any one of them occurred on a single admission.

State-level analyses cannot completely answer the question of whether allowing certified registered nurse anesthetists to provide anesthesia without supervision exposes patients to meaningful additional risks. By focusing on individual hospitalizations, however, it is possible to use Medicare claims to isolate any impact of opting out by anesthesia provider type.

It is possible that hospital managers systematically refer more difficult procedures to anesthesiologists and less difficult ones to nurse anesthetists. We therefore controlled for patient characteristics and procedure complexity.

We compared inpatient mortality rates between opt-out and non-opt-out states, stratifying by year and anesthesia arrangement. Anesthesiologists practicing alone were involved in more complex surgical procedures than certified registered nurse anesthetists practicing alone. Therefore, we adjusted anesthesiologist solo mortality rates by applying to the anesthesiologist solo group the nurse anesthetist case-mix for surgeries that the two providers had in common.

Frequency weighting was done at the diagnosis-related group level for each state, separately. T-tests were used to measure the differences in the adjusted mortality rates between opt-out and non-opt-out states within each stratum.

We also estimated logistic regressions using indicators for state opt-out status before and after opt-out and for anesthesia provider, to determine the effects of these variables on the probability of mortality and complications. Also included were the patient's age, sex, and race, along with year indicators and the procedure's anesthesia base units, to measure its complexity. The model was applied to surgical admissions pooled across all seven years in all opt-out and non-opt-out states.

Results

WHO PROVIDES ANESTHESIA We examined whether a state's decision to opt out of the supervision requirement resulted in different anesthesia arrangements. In our sample, the certified registered nurse anesthetist solo group provided anesthesia in 21 percent of surgeries in opt-out states and about 10 percent in non-opt-out states (Exhibit 1). Solo provision of anesthesia by nurse anesthetists increased over time in opt-out and non-opt-out states.

Although the absolute increase was roughly five percentage points in both opt-out and non-opt-out states, the proportional increase was larger in non-opt-out states (71 percent) than in opt-out states (28 percent). The growth of the solo share by certified registered nurse anesthetists in opt-out states came at the expense of

EXHIBIT 1

Percentages Of Surgical Anesthetics By Anesthesia Provider, In States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005

	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	17.6	40.7	41.7	7.0	47.3	45.8
2000	18.4	42.5	39.1	8.3	46.7	45.0
2001	20.2	42.0	37.8	9.2	45.3	45.5
2002	22.2	41.7	36.1	9.9	44.7	45.4
2003	22.9	42.5	34.7	10.3	43.7	46.0
2004	23.4	42.0	34.6	11.3	42.3	46.5
2005	22.5	42.8	34.7	12.0	41.5	46.5
1999–2005	21.0	42.0	37.0	9.7	44.5	45.8

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** Not all totals equal 100 percent because of rounding. CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together.

team anesthesia, while in the non-opt-out states it came at the expense of anesthesiologist solo anesthesia.

DIFFERENCES BY PATIENT TYPE OR PROCEDURE

Before comparing trends in outcomes, we examined whether the case-mix of certified registered nurse anesthetists and anesthesiologists differed by type of patient or procedure. Exhibit 2 shows patient characteristics as of 2005, stratified by anesthesia provider and state opt-out status. The figures have not been adjusted for the different diagnosis-related group surgical cases that are typical of the two types of anesthesia providers. With the exception of base units, the differences in patient characteristics between the certified registered nurse anesthetist solo and anesthesiologist solo groups, although statistically significant, were clinically minor and would not explain large differences in patient outcomes within opt-out and non-opt-out states.

With the exception of the prevalence of African American patients, the differences within provider groups across opt-out status were also

minimal.

In opt-out and non-opt-out states, the mean number of base units in the anesthesiologist solo group was about a full point higher than in the certified registered nurse anesthetist solo group ($p < 0.05$, or unlikely to be due to chance). This indicates that solo anesthesiologists were performing more complex or difficult procedures than the nurse anesthetist solo group. One might have expected higher relative complexity by nurse anesthetists practicing solo in opt-out states, given their higher proportion of cases.

However, many opt-out states are rural, and surgery and anesthesia in those states may be less complex overall than in more urban states. This is because patients with more difficult surgical procedures are referred to major urban hospitals with experienced surgical teams and technologies.

OUTCOMES FOR PATIENTS Given that the solo practice of nurse anesthetists did increase in opt-out states, we next determined whether there were any differences in patient outcomes by

EXHIBIT 2

Characteristics Of Anesthesia Patients In States That Did And Did Not Opt Out Of Physician Supervision, 2005

Characteristic	Opt-out states			Non-opt-out states		
	CRNA solo (n = 2,310)	MDA solo (n = 4,605)	Team (n = 3,736)	CRNA solo (n = 7,554)	MDA solo (n = 26,354)	Team (n = 29,511)
Age 75+	51%	48%	45%	44%	47%	44%
Male	41%	45%	44%	43%	45%	44%
African American	1%	2%	2%	8%	7%	11%
Base units ^a	7.2	8.3	7.6	7.2	8.4	7.6

SOURCE Authors' analysis of Medicare Parts A and B claims, 2005 limited data set. **NOTES** CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. All comparisons of CRNA solo with MDA solo are significant at the 95 percent confidence level. ^aBase units indicate the severity of the case; see text.

anesthesia arrangement. We started with mortality rates within each hospital for procedures that the two provider types had in common in opt-out and non-opt-out states.

In non-opt-out states, mortality rates for the three anesthesia arrangements followed a general downward trend throughout the seven-year period, from 3.1–3.5 percent to 2.2–2.8 percent (Exhibit 3). A general downward trend is also apparent in opt-out states. Of particular interest is the mortality trend for the certified registered nurse anesthetist solo group in opt-out states. The rate increased from 1999 to 2001—prior to the introduction of the opt-out provision—and decreased from 2001 to 2005. December 2001 was when the first state, Iowa, opted out of the supervision requirement.

MULTIVARIATE ANALYSES Exhibit 4 shows the results of the multivariate analyses for inpatient mortality and complications. It presents the odds ratios for each of the three provider groups in three different opt-out status conditions: non-opt-out states, opt-out states prior to opting out, and opt-out states after opting out. In addition to the provider group and opt-out status indicators, the model controlled for patients' age categories, sex, and race; anesthesia procedure base units; indicators for the ten highest-mortality diagnosis-related groups; and an annual time trend.

The reference group for the odds ratios for both mortality and complications was the anesthesiologist solo group in non-opt-out states. All eight comparison cells for mortality had odds ratios less than 1.0, which indicates that mortality occurred with lower probability in all other combinations of provider and opt-out status than it did with solo anesthesiologists in non-opt-out states (the differences are all significant at the 0.05 level). In opt-out states, there were no

statistically significant mortality differences between the periods before and after opting out.

Unlike mortality, complication rates did not differ between anesthesiologist and certified registered nurse anesthetist solo groups in non-opt-out states (Exhibit 4).¹⁷ Yet, as with mortality, nurse anesthetists practicing solo in opt-out states had a lower incidence of complications (odds ratios were 0.798 before opting out and 0.813 after) relative to solo anesthesiologists in non-opt-out states. These differences were statistically significant for both time periods.

In opt-out states, complication rates for the nurse anesthetist solo group were essentially identical to those for the anesthesiologist solo group. The difference between complication rates for nurse anesthetist solo and team anesthesia was also not statistically different in opt-out states.

Discussion

Linking the change in CMS reimbursement policy to changes in patient outcomes requires both that the proportion of surgical procedures for which certified registered nurse anesthetists alone provided anesthesia changed as a consequence of the policy change, and that the type of anesthesia provider affects the likelihood of in-hospital mortality or other adverse event. Our analysis does not support either of the two.

Instead, we found that from 1999 to 2005, the proportion of surgeries in which anesthesia was provided by nurse anesthetists with no anesthesiologist involvement increased by five percentage points in both opt-out and non-opt-out states. However, the rate of increase was nearly three times as great in non-opt-out states as in opt-out states because nurse anesthetist solo rates initially were lower in the former than in

EXHIBIT 3

Surgical Inpatient Mortality Rates (Per 100 Patients) By Anesthetist Arrangement, in States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005

Year	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	1.76	3.45	2.92	3.10	3.50	3.19
2000	2.50	3.67	1.79	3.16	3.21	2.58
2001	3.01	2.80	1.94	3.54	3.68	3.19
2002	2.26	2.72	2.15	3.09	3.44	2.95
2003	2.49	2.39	2.01	3.21	3.58	2.86
2004	1.86	3.82	2.03	2.84	3.20	3.08
2005	2.03	1.32	1.45	2.34	2.76	2.20

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. MDA solo and team mortality rates are based on CRNA case-mix. Inpatient mortality is attributable to anesthesia and all other causes.

EXHIBIT 4

Likelihood Of Death And Complications From Anesthesia, For Different Combinations Of Anesthesia Provider Groups And States' Opt-Out Status: Odds Ratios

Anesthesia provider	Mortality			Complications		
	Non-opt-out states	Opt-out states		Non-opt-out states	Opt-out states	
		Before opting out	After opting out		Before opting out	After opting out
MDA solo	1.00	0.797 ^a	0.788 ^a	1.00	0.824 ^a	0.818 ^a
CRNA solo	0.899 ^a	0.651 ^a	0.689 ^a	0.992	0.798 ^a	0.813 ^a
Team	0.959 ^a	0.708 ^a	0.565 ^a	1.067 ^a	0.927	0.903

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** MDA solo is anesthesiologist without certified registered nurse anesthetist (CRNAs). CRNA solo is CRNA without anesthesiologist. Team is anesthesiologist and CRNA working together. The model includes year, base units, diagnosis-related groups, and the patient's age, race, sex. Complications include patient safety indicators 1, 2, 4, 6, 10, 11, and 16 of the Agency for Healthcare Research and Quality; see text. ^aOdds ratio is significantly different from 1 for MDA solo ($p = 0.05$).

the latter. This implies that the increase in the certified registered nurse anesthetist solo share in opt-out states cannot be ascribed wholly, if at all, to the change in the CMS supervision policy.

Whatever forces are driving the growing share of nurse anesthetist solo cases, they appear to be different in the fourteen opt-out states than in the non-opt-out states. In opt-out states, the seven-percentage-point decline in team anesthesia resulted in more solo practice by both types of anesthetists. Anesthesiologists practicing solo explained about one-third of the decline in team anesthesia, and nurse anesthetists practicing solo accounted for the other two-thirds. Elsewhere in the country, team anesthesia rates were constant.

Despite the shift to more anesthetics performed by nurse anesthetists, no increase in adverse outcomes was found in either opt-out or non-opt-out states. In fact, declining mortality was the norm. Moreover, the mortality rate for the nurse anesthetist solo group was lower than for the anesthesiologist solo group in opt-out states both before and after opting out, although the difference was statistically significant only before the state opted out.

These results do not support the hypothesis that allowing states to opt out of the supervision requirement resulted in increased surgical risks to patients. Nor do the results support the claim that patients will be exposed to increased risk as a consequence of more nurse anesthetists' practicing without physician supervision.

We did find that case-mix complexity was different for the two types of providers. Anesthesia base units for procedures in which anesthesiologists practiced solo were a full point higher than for procedures in which certified registered nurse anesthetists worked alone.

Although base units might not completely de-

scribe the complexity of either surgical or anesthetic procedures, base units were associated with a statistically greater mortality risk in our multivariate model. We estimate that each one-point increase in procedure base units is associated with a 7 percent higher mortality risk.

To this extent, base units can capture a sizable part of the complexity and risk of the procedures. Moreover, we believe that using additional measures of complexity would not qualitatively change our results.

There were clearly differences between the opt-out and non-opt-out states that were not a consequence of their opt-out status. With the exception of the proportion of African American patients, it does not appear that these differences were primarily caused by patient characteristics such as sex and age.

Yet opt-out states had lower mortality and complication rates than non-opt-out states, even prior to opting out. This suggests that some unobserved difference existed between opt-out and non-opt-out states, perhaps related to the fact that opt-out states were more rural and tended to be located in the West and Midwest.

In any case, the policy conclusions supported by this study remain valid. In opt-out states, mortality and complication rates for the certified registered nurse anesthetist solo group did not vary greatly between the period before opting out and the period after. That means that our data do not support the hypothesis that patients are exposed to increased surgical risk if nurse anesthetists work without physician supervision.

Policy Recommendations

Our analysis of seven years of Medicare inpatient anesthesia claims suggests that the change in CMS policy allowing states to opt out of the

physician supervision requirement for certified registered nurse anesthetist reimbursement was not associated with increased risks to patients. In particular, the absolute increase in the provision of anesthesia by unsupervised nurse anesthetists in opt-out states was virtually identical to the increase in non-opt-out states, and the proportional increase was smaller in opt-out states.

This lends no support to the belief that a meaningful shift in provider shares occurred as a consequence of the policy change. Similarly, our analysis found no evidence to suggest that there is an increase in patient risk associated with anesthesia provided by unsupervised certified registered nurse anesthetists.

Both a change in the proportion of anesthesia provided by the different groups—nurse anesthetists alone, anesthesiologists alone, and

nurse anesthetists and anesthesiologists working in teams—and a difference in the outcomes of the different groups are necessary to conclude that the change in CMS policy led to changes in patient safety. Because our data provide no evidence to support either of these conditions, we conclude that patient safety was not compromised by the opt-out policy.

We recommend that CMS return to its original intention of allowing nurse anesthetists to work independently of surgeon or anesthesiologist supervision without requiring state governments to formally petition for an exemption. This would free surgeons from the legal responsibility for anesthesia services provided by other professionals. It would also lead to more-cost-effective care as the solo practice of certified registered nurse anesthetists increases. ■

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Cost Effectiveness Analysis of Anesthesia Providers

EXECUTIVE SUMMARY

- ▶ Anesthesiologists and certified registered nurse anesthetists provide high-quality, efficacious anesthesia care to the U.S. population.
- ▶ This research and analyses indicate that CRNAs are less costly to train than anesthesiologists and have the potential for providing anesthesia care efficiently.
- ▶ Anesthesiologists and CRNAs can perform the same set of anesthesia services, including relatively rare and difficult procedures such as open heart surgeries and organ transplantations, pediatric procedures, and others.
- ▶ CRNAs are generally salaried, their compensation lags behind anesthesiologists, and they generally receive no overtime pay.
- ▶ As the demand for health care continues to grow, increasing the number of CRNAs, and permitting them to practice in the most efficient delivery models, will be a key to containing costs while maintaining quality care.

IN THE UNITED STATES, anesthesia services are administered predominately by two types of providers. Anesthesiologists are physicians who have completed medical school, a clinical base year residency, and 3 years as a resident in an anesthesia program. Certified registered nurse anesthetists (CRNAs) are advanced practice nurses who have earned a baccalaureate degree, practiced at least 1 year as an acute care nurse, and have successfully completed a graduate-level nurse anesthetist program. These graduate programs have an average duration of 28 months and may be as long as 36 months. Currently, there are approximately 40,000 practicing anesthesiologists in the United States (Health Resources and Services Administration, 2007) and over 36,000 CRNAs (American

Association of Nurse Anesthetists [AANA], 2009). Both types of providers are critical to the safe, efficient provision of anesthesia services.

Anesthesia services are provided by CRNAs and by anesthesiologists in a variety of different delivery models. The delivery models vary by the degree of autonomy in which CRNAs may deliver anesthesia, as well as economic considerations. At one end of the spectrum, the CRNA may provide and bill for anesthesia services. At the other end, anesthesiologists may be the only providers administering and billing for anesthesia services in a particular practice setting. Between the two end points, CRNAs may work under varying degrees of supervision or medical direction. Delivery models may vary by

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2007). Sometimes the study identified those procedures which an anesthesiologist personally performed or directed, but may not distinguish whether medical direction was of CRNAs or anesthesiology residents (Silber et al., 2000). Given the low incidence of adverse anesthesia-related complications and anesthesia-related mortality rates in general, it is not surprising there are no studies that show a significant difference between CRNAs and anesthesiologists in patient outcomes.

Claims analysis for quality of care. In addition to reviewing the evidence from the literature, health care claims and discharge data were used to assess adverse anesthesia outcomes including death and anesthesia complications. Anesthesia complications were identified using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes (Donnelly & Buechner, 2001).

The Ingenix national database contains integrated medical and financial claims data from commercial payers in 2008. A total of 52,636 claims that included anesthesia were reviewed. There were no complications arising from anesthesia in these claims. The National Survey of Ambulatory Surgery (2006) contains information about surgical and nonsurgical procedures performed on an ambulatory (outpatient) basis in hospitals or freestanding ambulatory surgery centers for 2006. There are 52,233 sampled visits, representing almost 35 million total visits in the United States. Only one visit resulted in a complication from anesthesia. For that visit, anesthesia was provided by an anesthesiologist and a CRNA. The Healthcare Cost and Utilization Project Nationwide Inpatient Sample (2007) contains information for approximately 8 million hospital stays from about 1,000 hospitals sampled to represent a 20% stratified sample of

U.S. community hospitals. The unit of observation is an inpatient stay record rather than one specific procedure. It does not include anesthesia provider information. The percentage of complications is very low at 0.12% for the sample and 0.11% for the national estimate.

Quality of care by anesthesia providers is excellent. The incidence of adverse anesthesia-related complications and anesthesia-related mortality rates is very low. Our review of the literature revealed no studies that demonstrated a significant difference between CRNAs and anesthesiologists or differences between anesthesia delivery models in rates of anesthesia complications or mortality after controlling for hospital and patient factors.

Cost Effectiveness of Anesthesia Providers and Anesthesia Delivery Models

The total cost to provide required anesthesia services is compared across anesthesia delivery models. The most cost-effective approach is the one which produces the output or service at the lowest cost, while maintaining quality. An economically viable model is one where the revenues generated exceed the costs.

A review of the literature found that previous studies were largely based on simulation analyses. Abenstein, Long, McGlinch, and Dietz (2004), using outcome data from Silber et al. (2000), found that a medical direction model is more cost effective with respect to years of life saved than a model in which CRNAs act independently. The data were not based on mortality due to anesthesia complications, but mortality in general. Moreover, variation in delivery models may be correlated with variation in other factors affecting quality of care or patient risk.

Glance (2000) finds that an anesthesiologist alone is not a cost-effective delivery model.

Medical direction models are cost effective, with ratios varying optimally based on risk class of case. The Glance (2000) study used subjective estimates of patient risk in the analysis. Quintana, Jones, and Baker (2009) estimated the costs associated with a number of different delivery models, under the assumption outcomes are held constant. They found that anesthesiologist intensive forms of delivery are less efficient, and more likely to require subsidization by the hospital.

Using claims and national databases to determine what model is being used to provide anesthesia care is problematic. Hospital discharge data do not include the delivery model. There are difficulties in classifying types of supervision or medical direction by anesthesiologists in facilities that employ both CRNAs and anesthesiologists (Smith, Kane, & Milne, 2004). Recent studies have used surveys of hospital staffing patterns to determine provider type for obstetrical patients (Needleman & Minnick, 2008; Simonson et al., 2007). Even so, there are limitations on distinguishing models in facilities where CRNAs and anesthesiologists both practice. Needleman and Minnick (2008) differentiated hospitals where CRNAs and anesthesiologists both practiced based on the requirement that an anesthesiologist be present at the initiation of all planned cesarean sections. Simonson et al. (2007) resolved this dilemma by comparing hospitals with CRNA-only staffing to hospitals with only anesthesiologists.

Two complementary approaches to the analysis of the cost effectiveness of anesthesia delivery models were implemented. In the first, a stochastic simulation model that permits us to compare the cost effectiveness of the most prominent anesthesia delivery models while explicitly controlling for the factors that may influence the cost effectiveness was

Table 2.
Key Parameters Held Constant in Simulations

	Medicare	Medicaid	Private	Self-Pay
Payer proportions	0.45	0.1	0.4	0.05
Conversion factors	\$21.00	\$15.00	\$50.50	0
Costs				
Anesthesiologist	\$336,000/year	Nurse anesthetist	\$170,000/year	

Table 3.
Mean Values for Procedures by Setting

Setting	Base Units	Time Units
Inpatient	6.2	7.1
Outpatient surgery	4.0	4.0
Ambulatory surgery center	5.0	2.1

Table 4.
Inpatient Simulation with Average Demand (Results in Dollars)

Model Four per Station per Day	Yearly Total Revenue (12 stations)*	Yearly Total Costs (12 stations)*	Yearly Total Revenue Minus Total Cost (12 stations)*
Medical direction 1:4	\$5,401,171	\$3,048,000	\$2,353,171
Medical direction 1:3	\$5,593,158	\$3,384,000	\$2,209,158
Medical direction 1:2	\$5,673,606	\$4,056,000	\$1,617,606
Medical direction 1:1	\$5,697,316	\$6,072,000	-\$374,684
Anesthesiologist only	\$5,317,945	\$4,032,000	\$1,285,945
CRNA only	\$5,317,945	\$2,040,000	\$3,277,945
Supervisory 1:6	\$4,226,094	\$2,712,000	\$1,514,094

*Four per station per day is defined as four anesthetics per anesthetizing location per day.

A number of simulations across practice settings were conducted. The set-up for these simulations was the same (see Table 2).

The practice settings were defined by the characteristics of the procedures. Table 3 shows the mean values for the number of base units per procedure and the number of time units per procedure typically found in each setting.

For each scenario, first facility-level data to define the types and volume of anesthesia services provided at a typical facility over the course of 1 year was used. Then, the total cost to provide anesthesia services was modeled under each of the delivery models. Effi-

ciencies, under some delivery models, will vary depending on how many patients simultaneously receive anesthesia as well as how many patients receive anesthesia in a setting in a year. The simulation model will analyze the effect of different patient workload demands on the costs associated with the model. This is potentially important because the cost associated with a delivery model must be analyzed in the context of a patient workload, and the distribution of this patient workload. For example, if the delivery model consists of an anesthesiologist in a medical direction role for up to four nurse anesthetists, the average cost of

providing anesthesia will vary depending upon whether there is actual patient workload demand to support the model. If patient demand is such that the anesthesiologist is actually supervising the administration of anesthesia by four CRNAs simultaneously only 30% of the time, the costs will be higher than if there were patients to support full utilization.

The first scenario compares the results of the seven delivery models in an inpatient setting. For comparison purposes, we assume each delivery model operates at a facility with 12 distinct locations (stations or operating rooms). Hence, in a medical direction 1:4

Similar analyses were conducted but not reported here, for the outpatient and ambulatory surgical center settings. The overall conclusions regarding efficiency and economic viability were similar to those for the inpatient setting.

These results support the conclusion that the most cost-effective delivery model is CRNAs practicing independently. This model also produces the greatest net revenue. The supervisory model is the second lowest cost but reimbursement policies limit its profitability. The model would be almost as cost effective as CRNAs acting independently in settings where reimbursement is not an issue (e.g., veterans hospitals, military facilities). Other models, such as the medical direction 1:4 model, can do relatively well under conditions in which demand is sufficient to support full utilization. Under conditions when demand supports less than full utilization, almost all models will require a subsidy to remain viable. The CRNA acting independently is least likely to require a subsidy to remain economically viable. Moreover, we found in other experiments with the simulation model that when demand is highly variable, the net revenue of all models are adversely affected, but again the CRNA acting independently model is least likely to have negative net revenue. We also conducted sensitivity analyses around key model parameters, such as the salaries of the providers. The overall conclusions were robust across changes in key parameters of +/-10%.

Analysis of Claims Data

An analysis of claims data to compare the cost of providing anesthesia by provider type and by anesthesia delivery model was completed. Public and private insurance claims were used to estimate costs in inpatient and ambulatory surgery settings. The claims data identified surgical and

Table 7.
Billed Amount and Allowed Amount for Anesthesia per Procedure by Delivery Model

Delivery Model	N	Average Billed Amount	Average Allowed Amount
Anesthesiologist only	33,249	\$1,087.15	\$470.54
Medical direction 1:2-4	11,022	\$1,434.19	\$438.13
Medical direction 1:1	2,021	\$1,544.36	\$477.57
CRNA only	6,344	\$1,059.34	\$307.23

non-surgical procedures for which anesthesia was performed and other anesthesia-related services. The claims data indicated provider type (CRNA vs. anesthesiologist) for directly providing the anesthesia services. Some of the data included enough information to identify the delivery model.

The Ingenix national database contains integrated medical and financial claims data from commercial payers. Claims from year 2008 were analyzed. This database included anesthesia modifier codes to identify anesthesia delivery models.

Two payment variables were analyzed: billed amount and allowed amount. The billed amount is the amount billed by a provider or facility. For anesthesia services this typically includes base units for the procedure plus time units multiplied by a conversion factor. The allowed amount is the portion of submitted charges covered under plan benefits, or the contracted amount agreed to by providers. This amount is after discounts and not covered/excluded expenses, and before member responsibility. The allowed amount better reflects the dollar amount the provider will receive for the service from commercial payers.

The results for the average billed amount for anesthesia per procedure (see Table 7), demonstrate that the CRNA-only model is less costly, on average, than other models, followed by the

anesthesiologist-only model. The medical direction models are more costly.

Using a regression model to control for patient gender, age, facility type, and base units of anesthesia procedures, the CRNA-only model has a lower billed amount than the other models and the lowest to highest remains the same. Anesthesiologist-only billed amount is almost 4% higher than the CRNA only model, and medical direction models have billed amounts 28%-37% more than the CRNA-only model.

The results for the average allowed amount for anesthesia per procedure, also shown in Table 7, indicate that the CRNA-only model is less costly on average compared to all other models. Moreover, anesthesiologist-only model is now as costly as the medical direction models.

Using a regression model to control for patient gender, age, facility type, and base units of anesthesia procedures, the CRNA-only model has a lower allowed amount than the other models and the rank order from lowest to highest remains the same. The allowed amount for procedures when there is medical direction by an anesthesiologist of 2-4 CRNAs is 16% higher than the CRNA-only model. An anesthesiologist only and medical direction by anesthesiologist of one CRNA are 30%-33% higher than the CRNA-only model.

Table 9.
Baseline Values of Key Variables in the Anesthesia Graduate Education Model

Feature	CRNA	Anesthesiologist	Source
Program length	28 months	36 months	
Student/faculty ratio	7.4	2.2	AANA (2009); Franzini & Berry (1999)
Faculty salary	\$158,587	\$366,649	AANA (2008a); MGMA (2005)
Student opportunity cost at entry	\$52,455	\$120,000	Merritt Hawkins & Associates (2008); RN Magazine's 2009 Nurse Earnings Survey (Modern Medicine, 2009)
Attrition rate	7.3%/year	3%/year	AANA (2008a); Schubert (2007)

gists is to understand the education paths, and variants in those paths. A typical path for each is outlined briefly below.

- A CRNA must typically obtain a baccalaureate degree in nursing or relevant degree; must be licensed as a registered nurse; have at least 1 year of experience as an RN in an acute care setting; graduate from an accredited graduate-level nurse anesthesia educational program (average duration 28 months, may be as long as 36 months); and pass a national certification exam following graduation.
- An anesthesiologist must obtain a baccalaureate degree; spend 4 years in medical school leading to a degree in medicine (MD) or osteopathy (DO); complete a clinical base year residency; then complete 3 years of residency in anesthesiology. Board certification requires 4 years of residency in anesthesiology and passing the American Board of Anesthesiology exam.

The costs associated with traveling along those paths, both the direct costs and the opportunity costs (what the trainees could have been earning if they were not in an educational program), are estimated and included in this analysis. Also included is the productivity of the students which is estimated for the value of the student/resident services while being educated.

The literature on undergraduate and graduate education costs for CRNAs and anesthesiologists is presented in Table 8. Please note all estimates from the literature have been converted to 2008 dollars.

Education path cost estimates. Cost estimates of pre-anesthesia graduate education for CRNAs and anesthesiologists are taken from the literature. These include the costs of BA/BS/BSN degree, the cost of medical school for anesthesiologists, and the cost of a clinical base year residency for anesthesiologists.

Anesthesia graduate education cost model. An Education Path Cost Model for both CRNAs and MD anesthesiologists was constructed. For CRNAs, this estimate captures the average 28-month program that produces a CRNA. For anesthesiologists, the estimate captures the cost of the 3-year residency program in anesthesiology. The estimate is intended to capture the economic cost of education. This is the cost to society of obtaining an additional graduate. It is also constructed to approximate the additional costs that will be incurred to produce one more graduate. In that sense, it is an estimate of the marginal cost to society of producing a program graduate. The estimate consists of three major components:

- *Direct program costs.* This cost element consists of faculty salaries and benefits, liability insurance, and other direct costs of the graduate education program.

- *Student/resident opportunity cost.* This cost captures the value of the student's or resident's time while in the program. It represents what the student could be earning were the student not in the graduate program.

- *Student/resident productivity.* This is a measure of the value of the services the student or resident provides while in the graduate program. For example, the students and residents will be administering anesthesia. It is an offset to the other costs.

The graduate education cost model is driven by a number of key parameters: the student/faculty ratio, the salaries of faculty, the proportion of time the faculty allocates to instructing students or residents, the value of student's or resident's time (opportunity cost), the productivity of students or residents, program attrition, and program length.

Given these inputs, the model estimates the cost of a graduate from the program. Table 9 provides the baseline inputs used to estimate the cost of program graduates.

Table 10 displays the pre-anesthesia costs taken from the literature and estimates of the cost per graduate from the CRNA and anesthesiologist programs derived from the cost model. The costs are in 2008 dollars, and are undiscounted. Therefore, all the estimates are in 2008 dollars, but the estimates do not take into account

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Policy Perspectives

Competition and the Regulation of Advanced Practice Nurses

Policy Perspectives

Competition and the Regulation of Advanced Practice Nurses

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EXECUTIVE SUMMARY

The Federal Trade Commission (FTC or Commission) vigorously promotes competition in the health care industry through enforcement, study, and advocacy. Competition in health care markets benefits consumers by helping to control costs and prices, improve quality of care, promote innovative products, services, and service delivery models, and expand access to health care services and goods. While state legislators and policymakers addressing health care issues are rightly concerned with patient health and safety, an important goal of competition law and policy is to foster quality competition, which also furthers health and safety objectives. Likewise, to ignore competitive concerns in health policy can impede quality competition, raise prices, or diminish access to health care – all of which carry their own health and safety risks.

We are not suggesting that unfettered competition in health care services always leads to the best outcome for consumers. Actual or likely market failure, among other factors, may justify health and safety regulations. However, even well intentioned laws and regulations may impose unnecessary, unintended, or overbroad restrictions on competition, thereby depriving health care consumers of the benefits of vigorous competition. We thus urge policymakers to view competition and consumer safety as complementary objectives, and to integrate consideration of competition into their deliberations.¹

This policy paper builds on FTC staff competition advocacy comments that focus on proposed state-level changes to statutes and rules governing the “scope of practice” of Advanced Practice Registered Nurses (APRNs). Scope of practice rules determine the range of health care procedures and services that various health care professionals are licensed to provide under state law. In the case of APRNs, these rules establish both the range of services APRNs may deliver and the extent to which they are permitted to practice independently, or without direct physician supervision.² Because APRNs and other practitioners, including physicians, may be trained and licensed to provide many of the same health care services, scope of practice restrictions can limit the supply of those primary health care services, as well as competition between different types of practitioners.

FTC staff competition advocacy comments have addressed various physician supervision requirements imposed on APRNs. Physician supervision requirements may raise competition

1. See Section II.B., *infra*.

2. For a general review of APRN scope of practice restrictions, and their variation across the states, see, e.g., INST. OF MED., NAT’L ACAD. OF SCIENCES, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 98-103, 157-61 annex 3-1 (2011) [hereinafter IOM FUTURE OF NURSING REPORT].

capabilities. Effective collaboration between APRNs and physicians does not necessarily require any physician supervision, much less any particular model of physician supervision.

The competition concerns voiced in FTC staff's scope of practice advocacy comments are consistent with the policy analysis of a 2011 Institute of Medicine (IOM) report, *The Future of Nursing: Leading Change, Advancing Health*.⁷ The *Future of Nursing* report provides expert advice based on "[e]vidence suggest[ing] that access to quality care can be greatly expanded by increasing the use of . . . APRNs in primary, chronic, and transitional care,"⁸ and expresses concern that scope of practice restrictions "have undermined the nursing profession's ability to provide and improve both general and advanced care."⁹ The report found that APRNs' scope of practice varies widely "for reasons that are related not to their ability, education or training, or safety concerns, but to the political decisions of the state in which they work."¹⁰ The report recognizes FTC competition advocacy in this area and specifically exhorts the FTC and the Antitrust Division of the U.S. Department of Justice to pay continued attention to the competition issues raised by scope of practice regulations.

The FTC has looked to the findings of the IOM and other expert bodies – analyses based on decades of research and experience – on issues of APRN safety, effectiveness, and efficiency.¹¹ Based on those expert analyses and findings, as well as our own reviews of pertinent literature and stakeholder views, the FTC staff has urged state legislators and policymakers to consider the following principles when evaluating proposed changes to APRN scope of practice.

- Consumer access to safe and effective health care is of critical importance.
- Licensure and scope of practice regulations can help to ensure that health care consumers (patients) receive treatment from properly trained professionals. APRN certification and

7. IOM FUTURE OF NURSING REPORT, *supra* note 2. The IOM was established in 1970 as the health arm of the National Academy of Sciences. *Id.* at iv. The IOM web page, with links to general descriptions of the IOM, IOM reports, and other IOM activities, is at <http://www.iom.edu/>.

8. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27; *see also id.* at 88 ("Given current concerns about a shortage of primary care health professionals, the committee paid particular attention to the role of nurses, especially APRNs, in this area."). The extent to which APRNs and other professionals might augment the primary care workforce has been of policy interest for some time. *See, e.g.,* OFFICE OF TECH. ASSESSMENT, U.S. CONG., HEALTH TECH. CASE STUDY 37, NURSE PRACTITIONERS, PHYSICIAN ASSISTANTS, AND CERTIFIED NURSE-MIDWIVES: A POLICY ANALYSIS, 39 (1986) [hereinafter OTA HEALTH TECH. CASE STUDY] ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].").

9. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 4.

10. *Id.* at 5.

11. *See supra* note 6.

I. INTEREST AND EXPERIENCE OF THE FTC

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.¹² Competition is at the core of America's economy,¹³ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, and greater innovation. Innovation may include new and varied service delivery models that respond to the changing needs of the marketplace.

Health care is a major U.S. industry, and health care competition is crucial to the economy and consumer welfare. For these reasons, anticompetitive conduct in health care markets has long been a key focus of FTC law enforcement,¹⁴ research,¹⁵ and advocacy.¹⁶ As a result, the FTC has developed significant expertise regarding competition issues affecting the health care industry.

12. Federal Trade Commission Act, 15 U.S.C. § 45.

13. *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951) (“The heart of our national economic policy long has been faith in the value of competition.”).

14. *See, e.g.*, HEALTH CARE DIV., FED. TRADE COMM’N, AN OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2013), available at <http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf> (covering all actions through March 2013). For information regarding all FTC health care matters, see <http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>.

15. For example, in 2003, the FTC and the DOJ Antitrust Division held 27 days of hearings on health care and competition law and policy. *Competition in the Health Care Marketplace*, FED. TRADE COMM’N, <http://www.ftc.gov/news-events/events-calendar/2003/02/health-care-competition-law-policy-hearings> (last updated Apr. 10, 2013) (links to transcripts and other hearing materials); *see also Innovations in Health Care Delivery*, FED. TRADE COMM’N, <http://www.ftc.gov/news-events/events-calendar/2008/04/innovations-health-care-delivery> (last visited Feb. 28, 2014); *Emerging Health Care Competition and Consumer Issues*, FED. TRADE COMM’N, <http://www.ftc.gov/news-events/events-calendar/2008/11/emerging-health-care-competition-and-consumer-issues> (last visited Feb. 28, 2014); FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005), <http://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report>. A more comprehensive listing of FTC conferences and workshops is available at <http://www.ftc.gov/news-events/events-calendar/all>. Links to more FTC reports are available at <http://www.ftc.gov/policy/reports>.

16. FTC advocacy takes many forms, including letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, and amicus briefs. *See, e.g.*, Letter from FTC Staff to the Hon. Timothy Burns, La. House of Representatives (May 1, 2009), <http://www.ftc.gov/os/2009/05/V090009louisianadentistry.pdf> (regarding proposed restrictions on mobile dentistry); Written Testimony from the Fed. Trade Comm’n and U.S. Dep’t of Justice to the Ill. Task Force on Health Planning Reform (Sept. 15, 2008), <http://www.ftc.gov/os/2008/09/V080018illconlaws.pdf>; Brief of the Fed. Trade Comm’n as Amicus Curiae in *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, No. 1:12-cv-05743 (D.N.J. Mar. 11, 2013), available at <http://www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf>.

regulations.²² Related professional regulation issues also were the subject of prior FTC research²³ and competition advocacy.²⁴

II. BACKGROUND ON APRNS AND SCOPE OF PRACTICE ISSUES

II.A. Advanced Practice Registered Nurses

Most state practice laws recognize APRNs as a distinct category of nursing professional.²⁵ An APRN is a nurse practitioner with a graduate nursing degree, in addition to undergraduate nursing education and practice experience, who has been trained to provide a broad range of services, including the diagnosis and treatment of acute and chronic illnesses.²⁶ Nationally, “[m]ore than a quarter of a million nurses are APRNs . . . who hold master’s or doctoral degrees and pass national certification exams.”²⁷ In addition, APRNs generally attend nationally accredited education and training programs, and receive certification from nationally accredited certifying

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22. See, e.g., *id.* at ch. 2, pp. 25-28, 30-33 (“Through licensure requirements, states may restrict market entry by physicians and allied health professionals . . . and further limit the scope of authorized practice.” *Id.* at 25.).
23. See, e.g., CAROLYN COX & SUSAN FOSTER, BUREAU OF ECON., FED. TRADE COMM’N, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION (1990), http://www.ramblemuse.com/articles/cox_foster.pdf.
24. Comments of the Bureaus of Competition, Consumer Protection, and Economics of the Fed. Trade Comm’n to the Council of D.C. on Proposed Bill 6-317 to Create Specific Licensing Requirements for Expanded Role Nurses (Nov. 22, 1985); Brief of the Fed. Trade Comm’n as Amicus Curiae on Appeal from United States District Court, *Nurse Midwifery Associates v. Hibbett*, 918 F.2d 605 (6th Cir. 1990), *appealing* 689 F. Supp. 799 (M.D. Tenn. 1988). Based on analogous issues, the Commission also has enforced the antitrust laws in credentialing matters. See *In the Matter of Med. Staff of Mem. Med. Ctr.*, 110 F.T.C. 541 (1988) (Complaint) (alleging anticompetitive combination or conspiracy to deny credentials to nurse midwife). For a general discussion of these advocacies and underlying competition issues, see Daniel J. Gilman & Julie Fairman, *Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice*, 24 HEALTH MATRIX (forthcoming 2014).
25. Professional titles and nomenclature (e.g., “APRN,” “ARNP,” “nurse practitioner,” etc.), as well as APRN licensure criteria and scope of practice rules, have been converging nationally, although they still vary across the states. IOM FUTURE OF NURSING REPORT, *supra* note 2, app. D (regarding APRN Consensus Model and Final Report of the APRN Consensus Work Group and the National Council of State Boards of Nursing APRN Advisory Committee). The National Council of State Boards of Nursing posts updated maps of, e.g., states that recognize “APRN” as a professional title, states that permit independent APRN practice, and states that permit independent APRN prescribing. *APRN Maps*, NAT’L COUNCIL OF STATE BDS. OF NURSING, <https://www.ncsbn.org/2567.htm> (last updated Feb. 2014). As implemented in one state’s statutes and regulations, see, e.g., La. Rev. Stat. Ann. § 37:913(3)(a)(b) (2012); see also La. Admin. Code tit. 46, pt. XLVII, § 4505 (2012) (Louisiana State Board of Nursing regulations regarding APRNs).
26. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 23, 26.
27. *Id.* at 23. For an overview of APRN requirements generally, see *id.* at 26, table 1-1 (types of APRN practice) and 38-45.

independently.³⁴ While entry qualifications for APRNs are increasingly similar from state to state, the regulations that define APRN scope of practice continue to vary widely.³⁵ Some scope of practice restrictions are procedure-oriented, limiting APRNs' ability to prescribe medicines, refer for, order, or perform certain tests or procedures, or treat certain indications.³⁶ Other restrictions focus on the types of patients APRNs may see. For example, APRNs may not be allowed to "examine a new patient, or a current patient with a major change in diagnosis or treatment plan,

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34. TRACY YEE ET AL., NAT'L INST. FOR HEALTH CARE REFORM, RESEARCH BRIEF NO. 13, PRIMARY CARE WORKFORCE SHORTAGES: NURSE PRACTITIONER SCOPE-OF-PRACTICE LAWS AND PAYMENT POLICIES 2 (Feb. 2013), <http://www.nihcr.org/PCP-Workforce-NPs>.

As with other health care professionals, the states may define professional prerogatives and limits broadly or narrowly, through statutory law, administrative rules and decisions, and judicial decisions. *Compare, e.g.*, ALA. CODE §§ 34-21-81(4) (2012), which defines "Advanced Practice Nursing" as "[t]he delivery of health care services by registered nurses who have gained additional knowledge and skills through successful completion of an organized program of nursing education that prepares nurses for advanced practice roles as certified registered nurse practitioners, certified nurse midwives, certified nurse anesthetists, and clinical nurse specialists;" with LA. REV. STAT. ANN. § 37:913(3)(a)-(b) (2012), which describes APRN scope of practice as including:

- (i) Assessing patients, analyzing and synthesizing data, and knowledge of and applying nursing principles at an advanced level.
- (ii) Providing guidance and teaching.
- (iii) Working with patients and families in meeting health care needs.
- (iv) Collaborating with other health care providers.
- (v) Managing patients' physical and psychosocial health-illness status with regard to nursing care.
- (vi) Utilizing research skills.
- (vii) Analyzing multiple sources of data and identifying and performing certain acts of medical diagnosis in accordance with the collaborative practice agreement.
- (viii) Making decisions in solving patient care problems and selecting treatment regimens in collaboration with a licensed physician, dentist, or other health care provider as indicated.
- (ix) Consulting with or referring patients to licensed physicians, dentists, and other health care providers in accordance with a collaborative practice agreement.

See also LA. ADMIN. CODE TIT. 46, PT. XLVII, § 4505 (2012) (Louisiana State Board of Nursing regulations regarding APRNs).

35. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98.; *see also* NGA PRIMARY CARE PAPER, *supra* note 4, at 2.
36. For example, under Florida law, an APRN may "[m]onitor and alter drug therapies," FLA. STAT. § 464.012(3) (a), but may not prescribe controlled substances, FLA. STAT. § 83902(2) and 8390.5(1) (restricting controlled substance prescription to certain "practitioners" and defining practitioners to include physicians, but not APRNs).

practice more than a certain distance from the primary place of practice of his or her supervising physician.⁴³

Some supervision rules use different terminology to the same or similar effect. A state may require physician “delegation” of responsibilities to an APRN; Texas law, for example, imposes various supervision and delegation restrictions on APRN prescribing and diagnosis.⁴⁴ Alternatively, a state may impose certain “collaborative practice” requirements on APRNs, requiring that an APRN enter into a written agreement with a physician to define the parameters of the APRN’s permitted practice.⁴⁵ This can be viewed as a *de facto* supervision requirement, to the extent that the APRN cannot practice without securing the approval of an individual physician, whereas the terms of physician practice are in no way dependent on APRN input. In Louisiana, for example, an APRN must practice under a formal written collaborative practice agreement if he or she is to work to the full extent of APRN scope of practice, including “acts of medical diagnosis and prescription,” as otherwise permitted under Louisiana law.⁴⁶ West Virginia and Kentucky law require written collaborative practice agreements for APRN prescribing.⁴⁷

II.B. Competition Perspectives on Professional Regulations that Restrict APRN Scope of Practice

Together, licensure and scope of practice regulations for APRNs and other health care professionals serve important consumer protection objectives, including safety and quality. To meet fully the interests of health care consumers, however, requires weighing competition considerations when evaluating the potential costs and benefits of particular scope of practice

43. *Id.*, § 458.348(4) (c) (requires either on-site supervision or, “[a]ll such offices that are not the physician’s primary place of practice must be within 25 miles of the physician’s primary place of practice or in a county that is contiguous to the county of the physician’s primary place of practice. . . .”); *see also* MO. CODE REGS. ANN. tit. 20 § 2150-5.100 (2) (A)-(B) (2012) (“an APRN who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons” may not be more than 50 miles by road in federally-designated health professional shortage areas and not more than 30 miles by road otherwise).

44. TEX. OCC. CODE ANN. § 157.051 (2012).

45. FTC staff are not aware of any state that imposes comparable requirements of collaborative practice on physician scope of practice, although some states impose various requirements on physicians who elect to enter into collaborative practice agreements with APRNs or others. Whether a state explicitly requires a physician to supervise a collaborating APRN or not, asymmetrical collaboration requirements imposed on APRNs effectively create *de facto* supervision requirements where an APRN can only practice under terms agreeable to a licensed physician. For a general discussion of the relationship between supervision and collaboration requirements, *see* Lauren E. Battaglia, *Supervision and Collaboration Requirements: the Vulnerability of Nurse Practitioners and Its Implications for Retail Health*, 87 WASH. U. L. REV. 1127, 1137-38 (2010).

46. LA. REV. STAT. ANN. § 37:913(8)-(9) (2012) (requiring collaborative practice and a collaborative practice agreement).

47. KY. REV. STAT. § 314.042 (2013); W. VA. CODE § 30-7-15A (2012).

Quality of Care in Anesthesia

Synopsis of Published Information Comparing
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American Association of Nurse Anesthetists

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Section One

Summary of Pertinent Quality of Care Studies and Data

1. Needleman/Minnick OB Anesthesia Study in Health Services Research

[Needleman, J, Minnick, AF. "Anesthesia Provider Model, Hospital Resources, and Maternal Outcomes." *Health Services Research*. November 2008. DOI: 10.1111/j.1475-6773.2008.00919x.]

In the November 2008 online issue of *Health Services Research*, researchers Jack Needleman, PhD, MS, and Ann F. , PhD, RN, FAAN, published the results of a national study titled "Anesthesia Provider Model, Hospital Resources, and Maternal Outcomes." Using a geographically broad sample of hospitals in seven states, Needleman/Minnick sought to determine the ability of anesthesia provider models and hospital resources to explain maternal outcome variations. According to the researchers, "Given that almost 4 million U.S. women give birth annually, determining improvement strategies is important (National Center for Health Statistics 2005)." [page 3]

The results of the Needleman/Minnick study revealed that obstetrical (OB) anesthesia is equally safe in hospitals that use only Certified Registered Nurse Anesthetists (CRNAs) or a combination of CRNAs and physician anesthesiologists, compared with hospitals that use only anesthesiologists. These results confirmed the results of a 2007 study using Washington state data that revealed no difference in OB anesthesia complication or mortality rates between hospitals that use only CRNAs compared with hospitals that use only anesthesiologists (Simonson, et al.; see pp. 5-7 in this booklet.)

A. Rationale for Undertaking Study

According to the researchers, high cesarean delivery rates and extensive use of epidural pain relief make anesthesia an important component of obstetrical care. This study was undertaken:

- To identify any systematic differences in outcomes between hospitals using CRNA-only, anesthesiologist-only, and CRNA/anesthesiologist staffing models.
- To determine the ability of anesthesia provider models and hospital resources to explain maternal outcome variations.

B. Background

The study involved more than 1.14 million OB patients from 369 hospitals in seven states, including California, Florida, Kentucky, New York,

esthesia groups in making cost-effective staffing choices.

B. Background

For purposes of the study, Washington state hospital admission data for 1993-2004 were obtained from the Comprehensive Abstract and Reporting System database and merged with data from a survey of anesthesia or medical staff at hospitals where OB anesthesia was staffed by CRNAs only and hospitals where OB anesthesia was staffed by anesthesiologists only. A total of 134,806 patient records were analyzed, including those of 33,236 patients who were cared for by CRNAs only and 101,570 who were cared for by anesthesiologists only.

Regression analysis was used to adjust for independent variables such as hospital characteristics (geographic location, size, and teaching status), patient demographics (age, primary payer, and type of admission), and patient comorbidities.

In the study sample, there were 965 OB anesthesia complications and 17 deaths. According to the researchers, 76 percent of the complications were of a less serious nature per the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and only one of the deaths had an ICD-9-CM code associated with an anesthetic complication. The CRNA-only hospitals had a complication rate of 0.58 percent, while the anesthesiologist-only hospitals had a rate of 0.76 percent.

Significa Findings and Patterns. Several important findings and patterns emerged from the Simonson study:

- Hospitals with CRNA-only staffing had a lower rate of anesthetic complications than those with anesthesiologist-only staffing (0.58 percent vs. 0.76 percent, $p = .0006$). However, after regression analysis, this difference was not significant.
- The CRNA-only hospitals had a greater percentage of Medicaid, rural, teaching, urgent admission, and very young (under 17 years old) patients; the anesthesiologist-only hospitals had a greater percentage of emergency admissions and older mothers (over 35 years old).
- A substantially higher percentage of sicker patients were transferred to CRNA-only hospitals, a factor which could, potentially, affect the number of anesthetic complications in a facility. However, this did not prove to be the case.

C. Conclusions

Simonson et al. concluded the following:

- That OB anesthesia complications are no different between the

CRNA-only and anesthesiologist-only staffing models. "As a result, hospitals and anesthesiology groups may safely examine other variables, such as provider availability and costs, when staffing for obstetrical anesthesia." [page 1]

- That further study is needed to validate the use of ICD-9-CM codes for anesthesia complications as an indicator of quality.

3. Pine Study in the AANA Journal

[Pine, M, Holt, KD, Lou, YB. "Surgical Mortality and Type of Anesthesia Provider." *AANA Journal* 2003; 71:109-116.]

In the April 2003 *AANA Journal*, Dr. Michael Pine, a board-certified cardiologist widely recognized for his expertise in analyzing clinical data to evaluate healthcare outcomes, and a team of researchers published the results of a groundbreaking study titled "Surgical Mortality and Type of Anesthesia Provider." The study analyzed the effect of different types of anesthesia providers — specifically Certified Registered Nurse Anesthetists (CRNAs) and physician anesthesiologists — on the death rates of Medicare patients undergoing surgery.

The results revealed that patients are just as safe receiving their anesthesia care from CRNAs or anesthesiologists working individually, or from CRNAs and anesthesiologists working together.

A. Rationale for Undertaking Study

According to the researchers, the study was undertaken:

- To attempt to answer lingering questions about surgical patients' safety related to types of anesthesia providers, even though estimates of anesthesia-related deaths today are as low as 1 in 200,000 to 300,000 cases. [*To Err is Human: Building a Safer Health System*. Kohn, LT, Corrigan, JM, Donaldson, MS. Washington, DC: National Academy Press. 1999.]
- To provide state governors with valid scientific data to help them decide whether their respective states should opt out of the federal physician supervision requirement for nurse anesthetists. [*Federal Register*. Vol. 66, No. 219, pp. 56762-56769.] Without such data, governors must rely on older studies (see analyses of Bechtoldt and Forrest studies, pp. 10-13 in this booklet) or seriously flawed studies (see analysis of Silber/Pennsylvania study, pp. 25-32 in this booklet).

B. Background

The researchers studied 404,194 Medicare cases that took place from 1995-1997 in 22 states. Only cases with clear documentation of type of

supports "the conclusion that anesthesiologists improve anesthesia outcomes" is evidence of "either a woeful ignorance of the basics of data analysis or a cynical contempt for the intelligence of the intended audience." Defending his study, Dr. Pine wrote that his data actually found 34 deaths per 10,000 cases when CRNAs administered anesthesia while working together with anesthesiologists, and 45 deaths per 10,000 cases *when anesthesiologists worked without a CRNA*. He pointed out that this difference of 11 deaths per 10,000 cases was "even more impressive than the 7 deaths per 10,000 cases" difference cited by the ASA (see paragraph above), and that based on this data, "the AANA

to administer anesthesia unless a CRNA is present to prevent the excess mortality associated with physicians attempting to engage in the practice of nursing. However, unlike the ASA, the AANA respect for its audience to avoid making such unwarranted claims."

Dr. Pine reiterated his study's findings that after risk adjustment there is no statistically significant difference between CRNAs working individually, anesthesiologists working individually, or CRNAs and anesthesiologists working together. He added that his study's data support the conclusion that even when there are two anesthesia providers working together, substituting an anesthesiologist for a CRNA does nothing to lower the mortality rate. [Pine, M. Response to "ASA Preliminary Comment." www.aana.com. May 2003.]

4. Bechtoldt Study

[Bechtoldt, Jr, AA. "Committee On Anesthesia Study Anesthetic-Related Deaths: 1969-1976." *North Carolina Medical Journal*. 1981;42:253-259.]

A. Background

A 10-member Anesthesia Study Committee (ASC) of the North Carolina Medical Society reviewed approximately 900 perioperative deaths in that state over the eight-year period from 1969 to 1976. The ASC determined that 90 perioperative deaths were, to a certain extent, related to the administration of an anesthetic. The ASC did not study types of anesthesia-related outcomes other than death. Based on an ASC survey of hospitals, the ASC estimated that more than two million anesthetics were administered in North Carolina from 1969 to 1976.

The ASC defined "anesthetic-related" deaths as those in which the ASC determined that anesthesia was found to be a) the sole cause of death or b) the major contributing factor.

In categorizing cases, the ASC used information from death certifi-

cates and questionnaires completed by anesthesia providers of record. Based on that data, the ASC estimated that there had been one anesthetic-related death per 24,000 anesthetics administered.

The ASC used six different criteria to review the cases, including the following:

- type of anesthetic involved
- location where anesthesia was administered within the facility
- type of practitioner(s) involved in anesthesia administration
- surgical procedure or operation
- patient risk classification

B. Comparison of Outcome According to Provider Type

The ASC classified those who had administered anesthesia as follows:

- certified registered nurse anesthetist (CRNA) working alone
- anesthesiologist working alone
- CRNA and anesthesiologist working together
- surgeon or dentist
- unknown (in some of the cases, the type of practitioner administering the anesthetic was not identifiable based upon the information available to the ASC)

Bechtoldt reported that the ASC:

...found that the incidence among the three major groups (the CRNA, the anesthesiologist, and the combination of the CRNA working alone accounted for about half of the anesthetic-related deaths, the CRNA alone also accounted for about half of the anesthetics administered.

[page 257] [emphasis added]

Bechtoldt stated that the ASC's study included patients representing all risk categories. The study did not, however, address whether particular types of anesthesia providers (i.e., anesthesiologists or CRNAs) tended to encounter patients having particular risk factors. Because CRNAs working alone provided approximately half of the nearly two million anesthetics administered in the state during the period of the study, it is reasonable to believe CRNAs provided care to patients covering the full spectrum of physical status and anesthetic risk.

5. Forrest Study

[Forrest, WH. "Outcome — The Effect of the Provider." In: Hirsh, R, Forrest, WH, et al., eds. *Health Care Delivery in Anesthesia*. Philadelphia: George F. Company. Chapter 15. 1980:137-142.]

To obtain regional estimates of rates of mortality and severe morbidity totally associated with anesthesia with a precision of about 35% a nationwide study consisting of 290 hospitals should be selected. This size study would cost approximately 15 million dollars spread over a 5-year period.

8. National Academy of Sciences Study

This study was mandated by the U.S. Congress and performed by the National Academy of Sciences, National Research Council. The report to Congress stated: "There was no association of complications of anesthesia with the qualifications of the anesthetist or with the type of anesthesia." [House Committee Print No. 36, Health Care for American Veterans, page 156, dated June 7, 1977.]

9. Nurse Anesthetist Professional Liability Premiums

Based on a comparison of 1988 data from St. Paul Fire and Marine Insurance Company, at the time the country's largest provider of liability insurance for CRNAs (but no longer providing liability coverage for healthcare professionals), and 2004 data from CNA Insurance Company, currently the largest insurer of CRNAs, insurance premiums for nurse anesthetists have decreased nationally a total of 39 percent in that time span. (This pertains to claims-made coverage, typically for self-employed CRNAs.) The premium drop is detailed in the appendix titled, "Nurse Anesthetist Professional Liability Premiums: Premium Changes from 1988 to 2004," found at the back of this booklet. The appendix details premium information for CRNAs, both on a state-by-state basis and nationally.

The decrease in CRNA malpractice insurance premium rates demonstrates the superb anesthesia care that CRNAs provide. The rate drop is particularly impressive considering inflation, an increasingly combative legal system, and generally higher jury awards.

Section Two

Anesthesiologist Distortions Concerning Quality of Care

The following section discusses articles (by Abenstein and Warner; Silber et al.; Wiklund and Rosenbaum; and Vila et al.) that anesthesiologists have primarily cited to support their view that CRNAs should be anesthesiologist supervised, and that utilization of anesthesiologists improves anesthesia outcomes. As the following will demonstrate, however, none of the articles cites any credible scientific evidence that validates the anesthesiologists' position. In fact, two of the four articles do not even discuss the role of CRNAs in anesthesia care.

1. Abenstein and Warner Article in *Anesthesia & Analgesia*

[Abenstein, JP, Warner, MA. "Anesthesia providers, patient outcomes and costs." *Anesthesia & Analgesia*. 1996;82:1273-1283.]

A. Abenstein and Warner Distortions Concerning Minnesota Department of Health Study

The Minnesota Department of Health (DOH) study discussed earlier led to development of the Abenstein and Warner article. In its 1994 study of the provision of anesthesia services by CRNAs and anesthesiologists, the DOH reached four "key findings,"¹ including the following:

There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient outcomes based on type of anesthesia provider.

¹ "Limitations on the study made it impossible to fully evaluate the cost of service provided under each type of employment arrangement. However, there are some findings worth noting. Anesthesia providers are paid equivalent amounts per case under Medicare, and will likely under Medicaid, as well, when new guidelines are implemented. Reimbursement is declining to all anesthesia providers for federally funded programs and other third party payers are also beginning to negotiate lower reimbursement rates."

"There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient outcomes based on type of anesthesia provider."

"National and state health care reform are effecting [sic] the entire health care market in Minnesota. Although this study is the result of concerns over the changing market for anesthesia services, the primary forces driving these changes are effecting [sic] all of health care. For more than a decade, rising health care costs have been a major concern for state and federal programs. As both Medicare and Medicaid began to review their payment methodologies to reduce costs, payers and providers were prompted to seek new ways to control costs and, at the same time, maintain or improve the quality of services. Reduced payments by payers have brought about greater competition in many areas, including anesthesia services, and a growth in managed care concepts (i.e., negotiated fees, the formation of provider networks). This has been particularly true in Minnesota."

"As a result of the reduced reimbursement to anesthesia providers and the increased focus on cost containment, Minnesota hospitals have had to examine their budgets and attempt to cut costs. Hospitals began to look for new service delivery models that would encourage the cooperation of providers in their delivery of services, maintain high quality, and be cost effective. Consequently, several hospitals made the decision to terminate their CRNAs from their hospital staff and to contract for services. The providers are thus responsible for the billing and overhead costs, not the hospital, and for providing quality service to the patient. This decision, based on economics and the changing market, provide cost savings to these hospitals. The impact of health care market dynamics will continue as the market demands shift and develop both locally and nationally."

"In summary, anesthesia services continue to be provided primarily in a 'care team' approach using both anesthesiologists and CRNAs, with current risk levels remaining very low. The market and demand for both CRNAs and anesthesiologists is changing and we can expect continued flux in this market for several years" (pages 23-24 of the Minnesota DOH study)

these practices. . . . In summary, although the data, information, and analyses provided by the authors are interesting and provocative, I strongly disagree with their nearly unqualified statement that 'the anesthesia care team and hybrid practices appear to be the safest methods of delivering anesthesia care. This safety may be due, in part, to the rapid availability of physicians, especially during medical crises.' The question of how best to organize anesthesia care (or any other type of medical care) for achieving maximum patient safety has not yet been thoroughly examined. It is inappropriate to make claims such as those made by the authors based on such a paucity of data and analysis." [David M. Gaba, MD, Department of Anesthesia, Stanford University School of Medicine, Veterans Affairs Palo Alto Health Care System, Palo Alto, California; *Anesthesia & Analgesia*. December 1996, 82:1347-1348, Letters to the Editor.]

2. " . . . I question the validity of the conclusion reached by the authors [Abenstein and Warner] regarding the anesthesia care team in which they state, 'When the data are critically examined, the evidence is very supportive that the anesthesiologist-led anesthesia care team is the safest and most cost effective method of delivering anesthesia care. At this time, public policy decisions should encourage the development of anesthesia care teams where none exist, particularly in the rural areas, and assure the continued utilization of this patient care model'. . . . Unchallenged acceptance of the conclusion that evidence supports a specific method of anesthesia care delivery to be the 'safest and most cost effective' is misleading to patients, colleagues, and those responsible for shaping health care delivery policy. . . . the participation of certified registered nurse anesthetists (CRNAs) in delivery of anesthesia care would have ceased many years ago if there was evidence that this participation resulted in a less favorable outcome compared with anesthesia personally administered by an anesthesiologist." [Robert K. Stoelting, MD, Department of Anesthesia, Indiana University School of Medicine, Indianapolis; *Anesthesia & Analgesia*. December 1996, 82:1347, Letters to the Editor.]

C. *Abenstein and Warner Distortions Relating to the Bechtoldt and Forrest Studies*

The report submitted to the Minnesota Department of Health by the Minnesota Society of Anesthesiologists, and the Abenstein and Warner article, rewrote the findings of the Bechtoldt and Forrest studies that we summarized previously. Abenstein and Warner claim that the studies show that there were differences in the outcomes of care based on

type of provider, ***notwithstanding that the actual researchers came to the opposite conclusion.***

The Minnesota Department of Health report, in addressing the Bechtoldt study, stated:

Observed differences [in the incidence of anesthesia-related deaths] suggest that anesthesiologists and the CRNA-anesthesiologist care team were somewhat associated with lower rates of anesthesia-related deaths than CRNAs' [sic] working alone. However, given the absence of controls, the findings cannot be used to determine (1) whether the differences are greater than would be expected by chance, or (2) the extent that the type of anesthesia provider is responsible for the differences versus other factors. The author concluded that the incidence of patient death among these groups is 'rather similar.' [page 12, Minnesota DOH study]

Concerning the Forrest study, the Minnesota Department of Health stated:

Outcomes considered were deaths, complications, and intermediate outcomes. Ratios of the actual number of adverse outcomes (or deaths, morbidity, or weighted outcome scales) to the number predicted from selected patient and hospital characteristics (i.e., indirectly standardized outcomes ratios) for the two groups were compared and tested. The study concluded that, although there were some unadjusted outcome differences between the two groups, after controlling for patient and hospital characteristics, there were no statistically significant differences in outcomes between the two groups of hospitals defined on the basis of primary type of anesthesia provider. [page 11, Minnesota DOH study]

A December 1996 AANA *Journal* article by Denise Martin-Sheridan and Paul Wing, as well as the Zambricki article cited earlier, details the Abenstein and Warner article's numerous distortions and errors. Martin-Sheridan and Wing conclude that:

In general, the authors [Abenstein and Warner] reconfigure statistics and findings in the literature concerning outcomes of anesthesia care based on provider. If the best available research studies did not support their position, we feel it was inappropriate and misleading to reconfigure data upon which recommendations for policy decisions were made.

[Martin-Sheridan, D, Wing, P. "Anesthesia providers, patient outcomes, and costs: a critique." *AANA Journal*. 1996; 64(6):528-534, at page 533.]

posals, carefully evaluated the Silber study, and issued a report rejecting the study as any basis for requiring anesthesiologist supervision of CRNAs. The IRRRC stated that:

Based on our review of the 1992 *Medical Care* article, we have concluded, as its authors clearly state, it is a preliminary study and that caution should be taken in making any definitive conclusions. More importantly, the authors did not consider the scenario of an operating physician delegating the administration of anesthesia to a CRNA, or what expertise the operating physician should have in order to safely delegate anesthesia to a CRNA. Therefore, we do not believe this study should be used as justification for the significant change in practice for the administration of anesthesia.

The IRRRC further stated that:

There have been two studies, both completed over 20 years ago, that compared the outcomes of anesthesia services provided by a nurse anesthetist and an anesthesiologist. Neither of these studies concluded that there was any statistically significant difference in outcomes between the two providers. This conclusion was also reached by the Minnesota Department of Health, which recently completed a study on the provision of anesthesia services. In fact, most studies on anesthesia care have shown that adverse outcomes and deaths resulting from anesthesia has decreased significantly in the last several decades as [a] result of improved drugs and monitoring technology.

3. *New England Journal of Medicine* Articles (by Wiklund and Rosenbaum)

[Wiklund, RA, Rosenbaum, SH. "Medical Progress: Anesthesiology" (part one). *New England Journal of Medicine*. 1997;337(16):1132-1141. Wiklund, RA, Rosenbaum, SH. "Medical Progress: Anesthesiology" (part two). *New England Journal of Medicine*. 1997;337(17):1215-1219.]

These articles attempt to summarize key developments in the broad field of anesthesiology during the past 30 years. The articles focus on "preparation of patients for surgery, recent developments in anesthetic agents and techniques, multimodal pain management, and postoperative complications related to anesthesia."

The articles, however, do not attempt to compare patient outcomes by type of anesthesia provider. In fact, the articles do not discuss the

involvement or contributions of CRNAs. The articles, therefore, have no relevance to the issue of CRNA versus anesthesiologist quality, and certainly have no bearing on the question of whether CRNAs should be physician supervised.

The articles have some merit as an overview of anesthesiology developments during the past 30 years. For example, the authors discuss advances in applied research that have led to new technology, products, and techniques. In certain areas, however, the authors leave the path of an unbiased review of the specialty to make unsubstantiated or misleading comments about the unilateral contributions of anesthesiologists to the advancements achieved.

For example, part one of the article states in its opening paragraph that anesthesia-related deaths have decreased dramatically since the late 1960s, coinciding with a decision by the National Institutes of Health to "support training in clinical anesthesiology." While it makes logical sense that proper training should enhance outcomes in all disciplines, the reader is left to assume that it was this seminal event – physician training in anesthesiology – which has led directly to the decreased mortality rates mentioned.

In fact, many factors, some of which are discussed in the articles, have influenced the trend to improved anesthesia-related outcomes. The articles make little attempt to provide statistical support regarding the causes of outcome trends and do not compare outcomes based upon type of anesthesia provider, type of case, surgical setting, or patient physical status.

The authors make the blanket statement that:

Increasingly, anesthesiologists direct the preoperative assessment and preparation of patients for surgery with the aim of ensuring safe and efficient care while controlling costs by reducing unnecessary testing and preventable cancellations on the day of surgery. [page 1132]

While the value of preoperative patient assessment is indisputable, the authors reference only one article to substantiate their claim that anesthesiologist management of this process is particularly beneficial. In that case study [Fischer, SP. "Development and Effectiveness of an Anesthesia Preoperative Evaluation Clinic in a Teaching Hospital." *Anesthesiology*. 1996;85(1):196-206], cost-savings are reported through the use of an organized preoperative assessment clinic staffed by anesthesiologists and nurse practitioners, a service not previously available at this large, university-based medical center. Consequently,

closer examination clearly reveals that the study

- is not about anesthesia care provided by nurse anesthetists
- actually examines post-operative physician care.

A. Background

The study was conducted using data obtained from Health Care Financing Administration (HCFA) claims records. The study group consisted of 217,440 Medicare patients distributed across 245 hospitals in Pennsylvania who underwent general surgical or orthopedic procedures between 1991-94. Dr. Silber headed a research team that included three anesthesiologists.

B. Study Does Not "Compare Anesthesiologists Versus Nurse Anesthetists"

According to Dr. Longnecker, one of the anesthesiologist researchers: "The study ... does not explore the role of (nurse anesthetists) in anesthesia practice, nor does it compare anesthesiologists versus nurse anesthetists. Rather, it explores whether anesthesiologists provide value to the delivery of anesthesia care." [Source: Memorandum from Dr. Longnecker to Certified Registered Nurse Anesthetists in University of Pennsylvania Health System's Department of Anesthesia, October 5, 1998.]

Why, then, was such a misleading title ("Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?") chosen for the abstract? The answer: *for political reasons*. Consider these facts:

- The abstract was published in the midst of the controversy between anesthesiologists and nurse anesthetists over HCFA's proposal to remove the physician supervision requirement for nurse anesthetists in Medicare cases.
- The study was funded in part by a grant from the American Board of Anesthesiology, which is affiliated with the ASA. ASA vehemently opposes HCFA's proposal.

Why was the name of the abstract changed prior to publication of the paper in the July 2000 issue of *Anesthesiology*? Most likely for the following reasons:

- As Dr. Longnecker stated in his memorandum, the study was not intended to examine the question posed by the abstract's title.
- The study clearly could not and did not answer the question posed by the abstract's title.
- Pressure from AANA in the form of statements to the media and commentary published on the Internet forced the researchers and ASA to rename the paper for publication.

C. Problems with the Data

Careful examination of the "findings" reported in the paper reveal numerous problems.

Glaring Admissions. In the next to last paragraph of the paper, the researchers conclude that, "Future work will also be needed to determine whether the mortality differences in this report were caused by differences in the quality of direction among providers, the presence or absence of direction itself, or a combination of these effects." Boiled down, *this clearly is an admission by the researchers that the study does not, in fact, prove anything about the effect-positive or negative-of anesthesiologist involvement in a patient's overall care, let alone the patient's anesthesia care!*

This statement appears in a section titled "Discussion," which is devoted primarily to explaining away the limitations of the billing data used (HCFA's claims records comprise a retrospective database intended for billing purposes, not quality measurement) and the myriad adjustments for variables which the data required the researchers to make. According to the researchers, among other adjustments were those made for severity of illness and the effect of hospital characteristics.

The researchers, however, admit the following:

- "The accuracy of our definitions for anesthesiologist direction (or no direction) is only as reliable as the bills (or lack of bills) submitted by the caregivers."
- "We cannot rule out the possibility that unobserved factors leading to undirected cases were associated with poor hospital support for the undirected anesthetist and patient."
- "...if anesthesiologists had a tendency not to submit bills for patients who died within 30 days of admission, our results could be skewed in favor of directed cases."

These admissions by the researchers seriously limit the application of the data. They are also proof that ASA's use of data from this study, in advertising campaigns and lobbying efforts to discredit nurse anesthetists and frighten seniors, has been opportunistic, misleading, and ethically reprehensible at best.

Time Frame. Nurse anesthetists do not diagnose or treat nonanesthesia postoperative complications—they administer anesthesia. According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), anesthesia mishaps usually occur *within 48 hours of surgery*. The study, however, evaluated death, complication,

of the quality of anesthesia care provided by nurse anesthetists. It is a relevant measure of postoperative physician care, however.

Patients Involved More than One Procedure. For reasons not explained in the abstract, patients involved in more than one procedure were assigned to the nonanesthesiologist physician group if for any of the procedures the nurse anesthetist was supervised by a physician other than an anesthesiologist. It is impossible to measure the impact of this decision by the researchers on the death, complication, and failure to rescue rates presented in the abstract.

To emphasize the importance of this, consider the following hypothetical scenario: A patient is admitted for hip replacement surgery. A nurse anesthetist, supervised by the surgeon, provides the anesthesia. The surgery is completed successfully. Three days later the patient suffers a heart attack while still in the hospital and is rushed into surgery. This time the nurse anesthetist is supervised by an anesthesiologist. An hour after surgery, and for reasons unrelated to the anesthesia care, the patient dies in recovery. According to the researchers, a case such as this would have been assigned to the nonanesthesiologist group!

Patients Who Were Not Billed for Anesthesia Services. As noted in the discussion on death rates, most of the "undirected" cases had no bill for anesthesia care. The actual figure is 14,137 patients, or 61% of the 23,010 patients defined as undirected. The researchers' flimsy rationale for lumping all nonbilled cases in the undirected category is as follows: "The 'no-bill' cases were defined as undirected because *there was no evidence of anesthesiologist direction, despite a strong financial incentive for an anesthesiologist to bill Medicare if a billable service had been performed*" (emphasis added). Of course, one might ask how many of those cases were not billed because an anesthesiologist had a bad patient outcome.

Referenced Studies. The researchers claim that their research "results were consistent with other large studies of anesthesia outcomes." Interestingly, the two studies cited were by Bechtoldt (refer to page 10 of this booklet) and Forrest (refer to page 11 of this booklet). As indicated below, neither of these studies agrees with the conclusions reached by Dr. Silber and his team of researchers on the Pennsylvania study:

- Bechtoldt reported that the Anesthesia Study Committee (ASC) of the North Carolina Medical Society "...found that the incidence among the three major groups (the CRNA, the anesthesiologist, and the combination of the CRNA and anesthesiologist) to be rather similar. Although the CRNA working alone accounted for

about half of the anesthetic-related deaths, the CRNA working alone also accounted for about half of the anesthesiologists administered."

- After applying statistical tests to the results of research conducted by the Stanford Center for Health Care Research, Forrest stated: "Thus, using conservative statistical methods, we concluded that there were no significant differences in the outcomes between the two groups of hospitals defined by type of anesthesia provider. Different methods of defining outcome changed the direction of differences for two weighted morbidity measures."

Further supporting the argument that other studies do not agree with the purported findings of Silber and his fellow researchers is the following objective, third-party opinion offered by HCFA/CMS in the *Federal Register* on January 18, 2001: Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is, in part, the result of our review of the scientific literature which shows no overarching need for a Federal regulation mandating any model of anesthesia practice, or limiting the practice of any licensed professional." [p. 4685-4686]

D. HCFA/CMS Affirms that Study Not About CRNA Practice

In the anesthesia rule published in the January 18, 2001, Federal Register by HCFA/CMS, the administration dismissed all claims by ASA and the Pennsylvania study research team that the study examined CRNA practice and was relevant to the supervision issue. HCFA/CMS stated the following:

- "We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law." [p. 4677]
- "One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision." [p. 4677]
- "Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs." [p. 4677]

It is important that appropriate data on deaths and other adverse incidents related to office surgery be collected. Despite the Vila study's numerous methodological problems, the researchers' finding of significantly greater rates of mortality and adverse events in physicians' offices suggests that further study is needed.

Problems with the Study. Two areas of great concern with the Vila study are the following:

- The researchers' analysis largely consists of speculation unsupported by hard data, and
- The Vila study has major methodological flaws.

Vila et al. state that "anesthesiologists are present in nearly all ASCs and were present in the study reported by Hoefflin et al. in which there were no deaths in more than 23,000 office procedures [Hoefflin, SM, Bornstein, JB, Gordon, M. "General anesthesia in an office-based plastic surgical facility: a report on more than 23,000 consecutive office-based procedures under general anesthesia with no significant anesthetic complications." *Plast Reconstr Surg*. 2001;107:243-257]. This suggests that their presence may be a factor in more favorable outcomes."

The assertion that office surgery may be safer when an anesthesiologist is present is indefensible, for all of the reasons cited below.

- Anesthesiologist researchers have long made these kinds of assertions with little or no data to support their claims. For instance: Should Vila et al. be taken at their word that "anesthesiologists are present in *nearly all* (emphasis added) ASCs" simply because they say so? Where is the data to support this claim?
- "Presence" does not indicate "involvement." Do CRNAs actually administer (provide the hands-on care) in "nearly all" of Florida's ASCs, and are these facilities safer because this is so? Were CRNAs the main hands-on providers of anesthesia in the Hoefflin study? This pertinent information is not included in the Vila paper.
- According to the researchers themselves, "A statistical analysis of the impact of requirements for surgeon credentialing, office accreditation, and the presence of an *anesthesiologist* (emphasis added) could not be determined because of insufficient data on the patients who did not experience adverse incidents." Five sentences later, Vila et al. go on to speculate about how the presence of anesthesiologists may be a factor in more favorable outcomes, an assertion they had just acknowledged to be unsubstantiated by data!

- In stark contrast to what Vila et al. assert is a statement by George Bitar, MD, et al. in their study titled "Safety and Efficacy of Office-Based Surgery with Monitored Anesthesia Care/Sedation in 4778 Consecutive Plastic Surgery Procedures," published in the January 2003 issue of *Plastic and Reconstructive Surgery*. Bitar et al. concluded that "... office-based surgery with intravenous sedation, performed by board-certified plastic surgeons and nurse anesthetists, is safe. Appropriate accreditation, safe anesthesia protocols, and proper patient selection constitute the basis for safe and efficacious office-based plastic surgery."
- Also in stark contrast to Vila et al.'s assertion are written statements from 13 Florida-based office physicians protesting the study's implication that office surgery and anesthesia are not as safe as in ASCs. Collectively, these surgeons reported more than 35,000 procedures using CRNAs to provide the anesthesia care, without any patient deaths or significant complications. There were no anesthesiologists present for these cases. This begs the question: Is it office surgery in general that isn't safe, or merely surgery in a small number of selected physicians' offices?
- Vila et al. cite the adoption of office surgery guidelines by the Federation of State Medical Boards (FSMB) as a step toward improving patient safety. Significantly, the FSMB guidelines do not require anesthesiologist involvement in anesthesia care.
- Finally, in November 2000, an administrative law judge in Florida struck down a rule proposed by the Florida Board of Medicine that would have had the effect of preventing surgeons from using nurse anesthetists for procedures performed in certain office settings. In a 45-page opinion, Judge William Pfeiffer wrote: "In summary, there is no reliable data demonstrating that Level III office surgery is safer with an anesthesiologist than with a CRNA." (An appellate court overturned Judge Pfeiffer's decision on purely technical grounds unrelated to his factual finding.)

The Vila Study also suffers from numerous methodological flaws. Following are several examples:

- Vila et al.'s comments contain some speculation about possible reasons (e.g., presence of an anesthesiologist or type of facility) for differences in outcomes. These must be regarded as pure speculation because the data analyzed are inadequate to address these issues, as the researchers themselves acknowledge in their paper.
- In their current form the databases of procedures performed in ASCs and physicians' offices differ so substantially that an accurate comparison of the two is nearly impossible.

APPENDIX

Nurse Anesthetist Professional Liability Premiums

Premium Changes from 1988 to 2004

(Comparing 1988 data provided by St. Paul Fire and Marine Insurance Company to 2004 data provided by CNA Insurance Company)

State	1988 Premium	2004 Premium	Overall Change (%)
Alabama	2,537	2,092	-441 (-17)
Alaska	2,603	1,498	-1,105 (-43)
Arizona	5,414	3,445	-1,969 (-36)
Arkansas	1,196	2,034	838 (70)
California	7,148	3,901	-3,247 (-45)
Colorado	2,461	2,039	-422 (-17)
Connecticut	4,704	1,600	-3,104 (-66)
Delaware	2,689	2,228	-461 (-17)
D.C.	3,032	2,437	-1,056 (-35)
Florida	3,588	2,690	-898 (-25)
Georgia	2,219	1,491	-728 (-33)
Hawaii (1)	2,600	2,447	-153 (-6)
Idaho	4,221	2,132	-2,089 (-50)
Illinois	6,989	3,128	-3,861 (-55)
Indiana	5,809	1,753	-4,056 (-70)
Iowa	3,317	1,710	-1,607 (-49)
Kansas	3,272	1,471	-1,801 (-55)
Kentucky	2,972	1,809	-1,163 (-39)
Louisiana	3,358	2,703	-655 (-20)
Maine	2,598	1,380	-1,218 (-47)
Maryland	2,921	2,000	-921 (-32)
Massachusetts	2,678	1,571	-1,107 (-41)
Michigan	4,980	1,624	-3,356 (-67)

⁽¹⁾ St. Paul did not provide coverage in Hawaii until 1990

Minnesota	2,369	699	-1,670 (-70)
Mississippi	2,198	1,317	-881 (-37)
Missouri	7,806	3,456	-4,350 (-56)
Montana	3,872	1,371	-2,501 (-65)
Nebraska	2,228	1,279	-949 (-43)
Nevada	8,231	4,389	-3,842 (-47)
New Hampshire	2,530	2,294	-236 (-9)
New Jersey	5,013	3,318	-1,695 (-34)
New Mexico	2,249	2,559	310 (14)
New York	6,061	4,378	-1,683 (-28)
North Carolina	1,476	1,234	-242 (-16)
North Dakota	2,461	983	-1,478 (-60)
Ohio	5,392	3,045	-2,347 (-44)
Oklahoma	2,309	2,455	146 (6)
Oregon	5,737	2,214	-3,523 (-61)
Pennsylvania	1,771	1,145	-626 (-35)
Rhode Island	3,412	1,348	-2,055 (-60)
South Carolina	1,935	674	-1,264 (-65)
South Dakota	2,736	1,078	-1,658 (-61)
Tennessee	2,352	1,713	-639 (-27)
Texas	2,865	4,885	2,020 (71)
Utah	3,876	2,130	-1,746 (-45)
Vermont	2,330	1,191	-1,139 (-49)
Virginia	1,431	1,813	382 (27)
Washington	2,687	2,229	-458 (-17)
West Virginia	2,592	1,724	-868 (-33)
Wisconsin	2,744	1,013	-1,731 (-63)
Wyoming	3,947	2,866	-1,081 (-27)
TOTAL	177,916	107,983	-69,933 (-39%)