The Effect of Regulation on Innovation in Healthcare Delivery

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There is much debate around the effect laws and regulations have on innovation. One school of thought says that regulation generally stifles innovation by forcing entrepreneurs and prospective innovators to deal with rising compliance costs and excessive bureaucracy.[1] Others argue that regulation incentivizes innovation by creating a "moving target" that drives businesses to constantly improve the way they deliver services in order to keep up with evolving benchmarks for quality and maintain an edge on potential competitors.[1] A 2013 article published on the Forbes Magazine blog suggests that one way to judge whether a law or regulation will help or hinder innovation is to look at its intent.[2] According to the author, laws have a positive effect on innovation when they evolve with the time, creating an environment that encourages businesses to utilize and develop new business models that more effectively cater to the needs of consumers.[2] Conversely, regulations that primarily serve to preserve the status-quo or protect existing business models limit the power of innovation.[2]

The author of the Forbes blog post states, "Much of the

innovation occurring today revolves around products that didn't exist a generation ago. From the Internet to smart phones, apps and greater computing power, new businesses and business models are being created and all too often stifled by arcane laws created with good intentions, but now simply serve to protect old, status-quo businesses."[2] The author uses several case studies to prove his point ranging from the effort by cab companies to outlaw Uber to attempts by broadcast media to enact regulations banning the use of products that enable consumer to watch public TV on their computers. However, one industry the author does not touch on is healthcare. Nurses have always been an integral part of healthcare delivery, but since the early 1990s there has been unprecedented growth in the number and type of nurse-led models of care. Nurse-led innovations like nurse-managed clinics, retail clinics, and school-based health centers have proven effective in lowering healthcare costs and expanding access to services, but like other disruptive innovations, nurse-led models of care can either be helped or hindered by regulation. Laws and regulations that adapt with the times by allowing healthcare policymakers to tap all existing resources, including nurse practitioners, to respond to the needs of consumers promote innovation, while regulations that seek to preserve the status-quo for healthcare delivery curtail innovation.

Three of the most popular models of nurse-led care

are:

1) Nurse-Managed Health Clinics (NMHCs) – NMHCs are nonprofit community-based health centers primarily led by nurse practitioners. They offer affordable, accessible, high-quality primary care, health promotion, and disease prevention services to medically underserved populations, regardless of their ability to pay. Currently, there are approximately 250 of these clinics in operation across the country. About 60% of NMHCs are affiliated with schools of nursing and serve as low cost, community-based clinical sites for a range of health professions. Studies have shown NMHCs produce healthcare savings by reducing unnecessary healthcare utilization. For example, between 1990 and 2000, one NMHC was able to reduce emergency room visits by uninsured patients by 25%.[3] This led to an estimated cost savings of $13.9 million.[3]

2) Retail Clinics – Retail clinics are primarily for-profit healthcare facilities located inside retail locations, such as pharmacies and grocery stores. Today, there are about 2,300 retail clinics in 43 states and DC. The majority of retail clinics are led by nurse practitioners, with a smaller number staffed by physician assistants. The care encompasses basic primary care, preventive and wellness services, as well as some chronic disease monitoring and treatment. The clinics make care convenient and accessible by offering extended evening and weekend hours, visits that last 15-20 minutes, a transparent price

structure, and costs that are 40% to 80% lower than other healthcare settings.[4]

3) School-Based Health Centers (SBHCs) – SBHCs provide convenient, accessible, and comprehensive healthcare services where children and adolescents spend the majority of their time: in school. There are over 2,300 SBHCs in 49 states and DC; most are run by nurse practitioners or physician assistants.[5] Services are comprehensive, encompassing basic primary care, well-child visits, preventive screenings, immunizations, and behavioral health and oral health services, among others. Over 55% of SBHCs extend care beyond the school by serving patients from the surrounding community.[5] Studies have found that SBHCs reduce inappropriate emergency room use and hospitalizations for children with asthma.[6]

All three models of care could be classified as disruptive innovations because they represent a push away from the traditional model of physician-led care in favor of one that emphasizes the use of advanced practice nurses, such as nurse practitioners, and other non-physician providers. Because of their disruptive nature, nurse-led care advocates have had to deal with a whole series of antiquated laws and regulations designed to protect the status-quo and ensure that care continued to be physician-centered. For example, prior to the 1990s, nurse practitioners did not have the ability to write prescriptions, because the law stated that prescriptions

had to be written by a physician. Laws governing the writing of prescriptions and other healthcare practice issues are largely state-based. This means that nurse practitioners wishing to gain the authority to write prescriptions had to reform the prescribing laws and regulations in all 50 states. This long campaign finally came to an end in 2006 when Georgia became the last state to grant nurse practitioners prescriptive authority.

Another major sticking point has been managed care participation. Again, prior to the 1990s, most state laws only allowed physicians to act as primary care providers in managed care provider networks and, even when states began to permit nurse practitioners to act as primary care providers, most managed care organizations would not contract with nurse practitioners practicing in a primary care role. Although, there has been progress in this area, 25% of the nation's major managed care organizations still will not contract with nurse practitioner primary care providers.[7] Finally, even though nurse practitioners can prescribe in every state, 29 states have passed laws requiring nurse practitioners to enter into a collaborative agreement with a physician before they can prescribe.[8] These agreements, which often require physicians to review the charts of patients seen by nurse practitioners and perform supervision, are a way for physicians to maintain some control over how nurse practitioners deliver care.

All of the above laws and regulations have negatively

impacted healthcare delivery innovations, like nurse-managed clinics, retail clinics and school-based health centers, most of which are run by nurse practitioners. Laws and regulations limiting prescriptive authority for nurse practitioners restricted the ability of these clinics to expand access and created additional roadblocks for consumers. The refusal of some managed care organizations to contract with nurse practitioner primary care providers means that many clinics cannot access the sources of third-party reimbursement available to other providers and, in some cases, physician collaboration requirements have caused nurse-led clinics to close. For example, one retail clinic had to close when the state it was located in enacted a regulation stating that nurse practitioners must practice within 15 miles of their collaborating physician's primary office. The physician collaborating with the clinic's nurse practitioners retired and the clinic could not find a replacement physician within the 15 mile radius. Therefore, the clinic was forced to close, leaving hundreds of patients living in the rural area without a healthcare access point.

More recent efforts have, however, accelerated the pace of innovation and transformation within healthcare delivery. Two of the most prominent examples are the Institute of Medicine's (IOM) 2010 report entitled, "The Future of Nursing: Leading Change, Advancing Health," and the Affordable Care Act (ACA). Faced with the nation's deepening primary care physician shortage, both

the IOM report and the ACA contain language encouraging the use of nurse practitioners in primary care roles, as well as incentives for nurse-led models of care. Although not an official regulatory body, the IOM wields considerable influence on state and federal healthcare policy. The Future of Nursing report highlights the benefits of nurse-led models of care extensively. For instance, the report mentions retail clinics over 30 times, while stating that retail clinics are, "a desirable service-delivery mechanism providing accessible, less costly, evidence-based services."[9] The ACA contained provisions authorizing special funding for nurse-led clinics, a graduate nurse education demonstration project that involved nurse-led clinics and language prohibiting discrimination by managed care organizations against nurse practitioners acting as primary care providers.[10]

In the six years since the passage of the ACA and the publication of the IOM report, the attitude of the states toward nurse-led models of care has improved significantly. The number of nurse-led clinics in operation has also grown tremendously. In terms of regulation, the number of states allowing nurse practitioners to practice and prescribe independent of physician collaboration has grown from 17 to 21 plus DC. Likewise, the percentage of managed care organizations contracting with nurse practitioners as primary care provider has increased from 50% to 75% since 2010. According to recent research, greater utilization of nurse practitioners and models of

nurse-led care has led to an increase in access for consumers and an overall decrease in the cost of care. [11, 12] Much of the impetus for these changes can be traced back to a willingness on the part of policymakers to enact laws and regulations that encourage the use of every available healthcare provider to meet the needs of consumers, rather than protecting the status quo.

As the nation moves forward into a new administration, newly elected state and federal policymakers must resist the temptation to maintain the status quo by enacting laws and regulations that promote innovation in all areas, including healthcare delivery. One increasingly important issue is telehealth. Many states have enacted telehealth regulations, which are tied to a model of physician-directed care. To encourage innovation, new telehealth laws should be worded in a way that moves beyond traditional healthcare delivery and allows nurse practitioners, as well as other non-physician providers to fully access the technology. As William Pollard said, "Learning and innovation go hand in hand. The arrogance of success is to think that what you did yesterday will be sufficient for tomorrow."[13]

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