

among healthcare providers, including net commercial prices for their services. This likely would be informative, but it's unclear whether such efforts would affect prices or quality.

In Massachusetts, a special commission recommended the regulation of hospital prices to keep costs in line.<sup>51</sup> “Market forces solutions aim to correct distortions and inefficiencies in the marketplace by increasing competition, so that differences in prices reflect so-called warranted reasons for price variation. It is important to foster competition among healthcare providers and insurers in light of increasing consolidation in healthcare markets, both in Massachusetts and nationally,” their report says.

### 6.1 Provider Consolidation: Discussion Questions

- Do hospital mergers typically raise prices?
- Does hospital-physician consolidation typically raise prices?
- Does provider consolidation make it more difficult for payers to create narrow networks?
- Are the arguments valid that consolidation and scale are necessary for hospitals to survive in an era of accountable care, population health management, and high IT investment?
- What has been the impact of the Massachusetts Health Policy Commission on consolidation and costs?
- Should the size of the FTC be increased substantially to deal with provider consolidations?
- Should regulators not only restrict potential mergers but actively break up existing ones?
- What would be the impact of site-neutral pricing on consolidation? On healthcare costs?
- Does the employment base of hospitals restrain state government antitrust action?
- Should the government use the Essential Hospital label to reduce monopolistic power?
- Could California's case against Sutter Health be a game-changer?

## 7. Provider Regulation as A Cost Driver

### Overview

- Estimated that up to 20% of total healthcare costs are due to regulations
- Too many regulations contribute to physician burnout and take resources away from patient time
- Many regulations are outdated and do not reflect the current reality of the healthcare landscape
- Other regulations do not contribute to quality improvement
- The Trump administration has signaled interest in reducing regulatory burden for healthcare providers

### Scope of Practice

- There is wide variation in scope-of-practice (SOP) regulations across states. In 22 states, nurse practitioners (NPs) are permitted to provide care independently.<sup>52</sup> Other states do not permit NPs to practice without collaborating with, or being supervised by, a

physician. Many of these states require written practice protocols, and they sometimes restrict the number of NPs with whom a physician may collaborate. Still other states allow NPs to practice independently but permit them to prescribe medicines only if they are collaborating with or supervised by a physician.

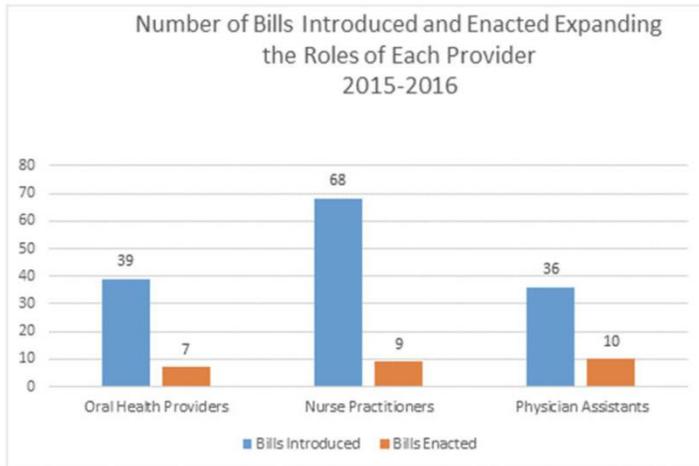
- Many argue that widening the SOP for healthcare professionals such as NPs, physician assistants, and pharmacists allows for patients to be treated at a lower cost while easing the strain of the physician shortage and maintaining clinical outcomes.
  - When discussing multidisciplinary teams in healthcare, many have also emphasized the importance of including other healthcare professionals such as dietitians, physical therapists, occupational therapists, psychotherapists, and social workers. However, there is still a lack of evidence regarding the cost-effectiveness and the changes in clinical outcomes related to the implementation of such programs.
- Increasing SOP often meets resistance from physicians' groups nervous of losing some of their autonomy, exclusivity, and prestige.
- Other objections include that it allows for the possibility that patients might receive healthcare services of an inferior quality because the healthcare professionals who are providing them do not have the same level of training as physicians.
  - However, healthcare teams in which registered nurses work independently, yet in tight collaboration with practicing physicians, have not only been reported to provide adequate healthcare services and diagnoses to patients; they have also been shown to do so with equal or increased levels of patient satisfaction, with no significant differences in clinical outcomes. These teams also yield the promise of improved cost-efficiency allowing for more medical services to be performed by lower paid professionals.
  - The results of physician assistant implementation in healthcare teams have been extremely promising throughout the world in all or most countries where they are present.<sup>53</sup> In the UK, a small team of physician assistants has successfully provided a large number of patients with similar quality healthcare services as medical residents and doctors. When asked, patients reported that they were highly satisfied with the attention they received and were impressed by the empathy with which their healthcare providers had treated them. In addition, the doctors working with the team of physician assistants reported excellent professional interactions with their new staff members, showed no resistance to the prolongation of their contract, and were very appreciative of the help that they were providing them.
- In one study, 25% of doctors willingly affirmed that their SOP is too wide.<sup>54</sup> Recent efforts have emphasized that all providers should be working at the "top of their license" – meaning that they focus on providing care that requires their level of education and training rather than spending time providing care that could effectively be done by other providers, as this would increase efficiency in care delivery.

- Many primary care physicians, if asked, “What percentage of your time do you perform functions that require a medical degree,” will give an answer hovering around 50 percent.<sup>55</sup>
- A 2014 white paper from the Bay Area Council Economic Institute finds that allowing nurse practitioners to practice to the full extent of their education and training could save California \$1.8 billion on preventive care visits alone over 10 years while increasing the number of preventive care visits by 2 million per year.<sup>56</sup>
- Although prices could decrease for a given service from an NP with full practice authority, the amount of services provided could increase, raising the overall cost of healthcare.
  - Literature suggests that healthcare prices drop after SOP laws are relaxed, potentially because of increases in the supply of NPs, leading to more competition. However, total spending might increase as access to care improves and utilization increases. So, the total effect on spending is unclear.
- In a Stange (2014) study, despite no effect on prices, total spending on office visits was 4.3 percent higher in states where NPs have independent prescriptive authority.<sup>57</sup> That figure represents spending in all office-based settings and for physician and NP visits.
- Given the relative price differences across office visits and ED visits, the reduction in ED visits could counterbalance a small increase in office-based spending.
- Spetz et al. (2013) found that total spending for a 14-day episode of care for a specific set of relatively minor illnesses that can be treated at retail clinics cost \$543 in states without NP independence, \$484 in states with independent practice authority, and \$507 in states with both independent practice and independent prescriptive authority.<sup>58</sup> States granting NPs independent prescriptive authority had higher rates of prescriptions filled and higher prescription costs, as well as higher overall costs, than those with only practice independence, which is consistent with findings in the Stange (2014) study. Nevertheless, total spending in states with complete independent prescriptive authority was still slightly lower than in those with no independence, which could reflect lower prices in the independent states because of fewer restrictions on care.
- A 2015 RAND study found that the effect of SOP laws on total healthcare spending is inconclusive.<sup>59</sup> Prices do appear to go down slightly, while utilization increases because of improvements in access to care. Spending in 9 states that grant NPs full prescriptive authority does seem to increase slightly for some services, such as office visits. However, ambulatory care sensitive (ACS) emergency visits tend to drop. NP independence might reorient spending toward higher-value services. If, as the studies suggest, NP full practice authority leads to more office-based primary care visits and checkups and fewer ACS emergency visits, then value per dollar spent should increase; however, there is not enough evidence to know definitively. It does appear that restrictive SOP laws could, in some states, force NPs to pay a significant share of practice revenues to their collaborating physicians.

#### Recent Activity

- Two dozen SOP laws were enacted in 2017.<sup>60</sup>

- In 2018, state legislators have introduced more than 80 bills relating to SOP for nurse practitioners, physician assistants, dental hygienists, dental therapists, community health workers, community paramedics, and peer support specialists.<sup>61</sup>



## Evaluation and Management Coding System

- Evaluation and management (E/M) services are visits performed by physicians and non-physician practitioners to assess and manage a beneficiary's health. Medicare paid \$32.3 billion for E/M services in 2010, representing nearly 30 percent of Part B payments that year.
- E/M services are divided into broad categories that reflect the type of service, the place of service, and the patient's status. These broad categories of E/M services are known as visit types. Most visit types are further divided into three to five levels, which reflect the complexity of a visit and correspond to Current Procedural Terminology (CPT) codes for billing purposes. Higher level codes within a visit type correspond to increased complexity of the E/M service and higher payment rates.
- The E/M coding system was established twenty years ago to try to counter the "upcoding" of visits to more complex levels that generate higher payment. It has been well established that, perversely, these guidelines actually promote upcoding as physicians take advantage of the EHR's ability to "cut and paste"—in essence, to provide clear documentation for services not actually provided during a visit for which a physician is seeking too much payment.
- In 2012, the Office of Inspector General (OIG) reported that physicians increased their billing of higher level codes, which yield higher payment amounts, for E/M services in all visit types from 2001 to 2010.<sup>62</sup> The Centers for Medicare & Medicaid Services (CMS) found that E/M services are 50 percent more likely to be paid for in error than other Part B services; most improper payments result from errors in coding and from insufficient documentation.

# TheZetemaProject

- A 2010 study discovered Medicare inappropriately paid \$6.7 billion for claims for E/M services in 2010 that were incorrectly coded and/or lacking documentation, representing 21 percent of Medicare payments for E/M services that year.<sup>63</sup>
- 42 percent of claims for E/M services in 2010 were incorrectly coded, which included both upcoding and downcoding (i.e., billing at levels higher and lower than warranted, respectively), and 19 percent were lacking documentation.<sup>64</sup>
- Additionally, claims from high-coding physicians (i.e., those who consistently billed higher level codes for E/M services) were more likely to be incorrectly coded or insufficiently documented than claims from other physicians.<sup>65</sup>

## Recent Activity

- Some argue the E/M coding system is too convoluted, not only leading to fraud, but also increasing rates of accidental upcoding and downcoding.<sup>66</sup>
- One suggested response is that most medical billing for simple office services and procedures should be eliminated entirely in favor of point-of-care payment strategies, such as healthcare payment cards (e.g., a debit card) for all types of payers.<sup>67</sup>

## Certificates of Need

- Certificate of Need (CON) programs are aimed at restraining healthcare facility costs and facilitating coordinated planning of new services and facility construction.<sup>68</sup> Many CON laws initially were put into effect across the nation as part of the federal "Health Planning Resources Development Act" of 1974. Despite numerous changes in the past 30 years, most states retain some type of CON program, law, or agency as of 2016.
- CON laws were intended to correct for this problem and stem the "medical arms race" that had ensued. However, the adoption of the Medicare inpatient prospective payment system (PPS) in the 1980s eliminated the reimbursement incentive for providers to expand, and the market forces of managed care in the 1990s played a significant role in correcting for excess capacity.
- In addition to cost-control justifications, proponents of CON regulations argue that these restrictions help many facilities cross-subsidize care to indigent patients, as well as promote quality and access to care.<sup>69</sup>
- However, changes to the healthcare industry with respect to provider reimbursement and healthcare delivery may have fundamentally altered markets, at least partially invalidating these justifications and potentially transforming CON regulations into competitive barriers to entry that do more harm than good.
- In recent decades, the theory that CON restrictions can effectively control healthcare costs has been largely discredited, and the federal agencies tasked with monitoring competition in healthcare have discouraged the use of such restrictions, yet state laws in this area remain relatively unchanged.<sup>70</sup>
- Both the Federal Trade Commission (FTC) and the Department of Justice (DOJ) have taken the position that CON programs "...can actually increase prices by fostering anticompetitive barriers to entry."<sup>71</sup>

- The ACA does not explicitly address the problems posed by CON restrictions; rather, it contains provisions designed to stimulate competition in other ways.

## Recent Activity

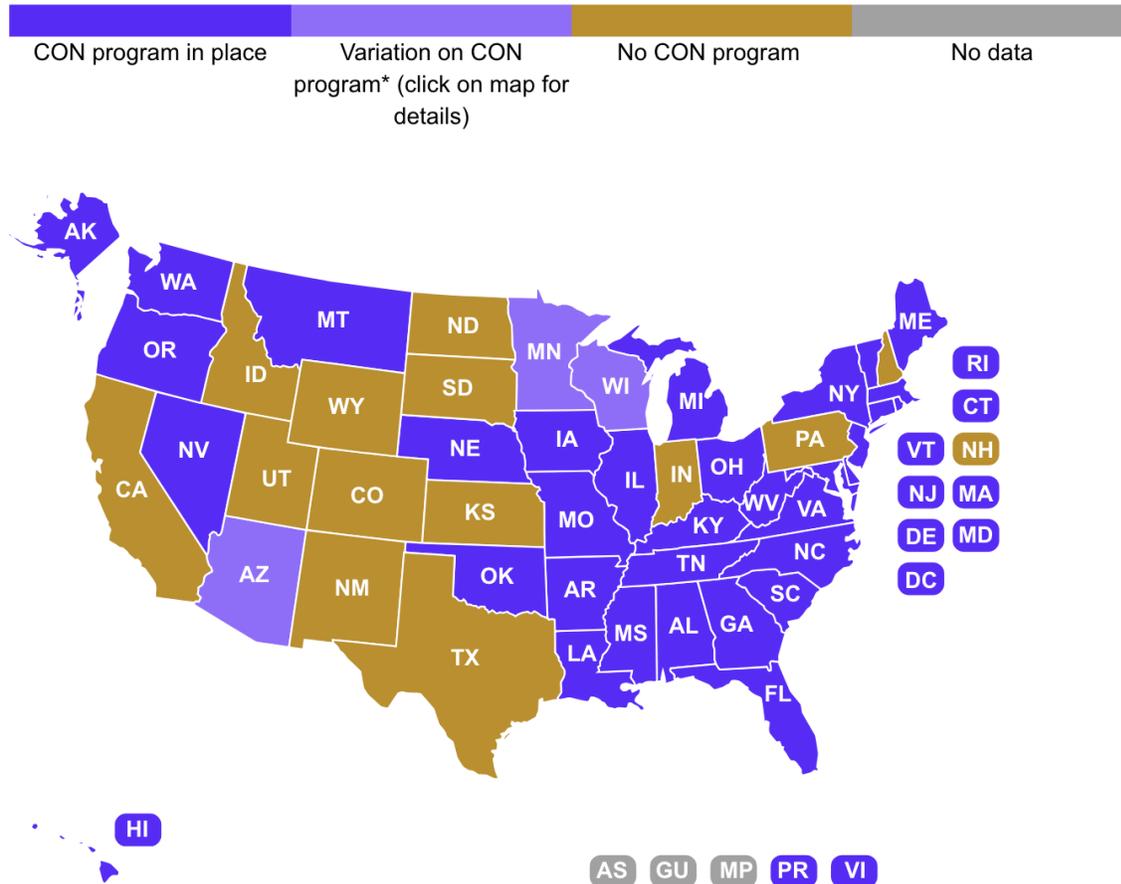
- 14 states have discontinued their CON programs. New Hampshire was the most recent repeal, effective 2016.<sup>72</sup>
- 34 states currently maintain some form of CON program. Puerto Rico, the US Virgin Islands, and the District of Columbia also have CON programs.
- 3 states have variations

### ARGUMENTS IN FAVOR AND AGAINST CON LAWS

Arguments in Favor of CON Laws	Arguments Against CON Laws
<ul style="list-style-type: none"> <li>■ Health care cannot be considered as a “typical” economic product.</li> <li>■ Most health services (like an x-ray) are “ordered” for patients by physicians, patients do not “shop” for these services the way they do for other commodities.</li> <li>■ The American Health Planning Association (AHPA) argues that CON programs limit health-care spending. CON programs can distribute care to areas that could be ignored by new medical centers.</li> <li>■ CON requirements do not block change, they mainly provide for an evaluation, and often include public or stakeholder input.</li> </ul>	<ul style="list-style-type: none"> <li>■ By restricting new construction, CON programs may reduce price competition between facilities and keep prices high.</li> <li>■ Some changes in the Medicare payment system (such as paying hospitals according to Diagnostic Related Groups – “DRGs”) may make external regulatory controls unnecessary by sensitizing health care organizations to market pressures.</li> <li>■ CON programs are not consistently administered.</li> <li>■ Health facility development should be left to the economics of each institution rather than being subject to political influence.</li> <li>■ Some evidence suggests that lack of competition encourages construction and additional spending.</li> <li>■ Potential for CONs to be granted on the basis of political influence, institutional prestige or other factors apart from the interests of the community.</li> <li>■ It is not always clear what the best interests of the community entail.</li> </ul>

Source: CON-Certificate of Need State Laws, NCSL, August 25, 2016

## CERTIFICATE OF NEED STATE LAWS



Source: NCSL, August 2016

### Meaningful Use (MU)

- The MU program was established in 2009 as part of the HITECH Act. MU requires eligible hospitals and professionals to meet certain measures in order to demonstrate meaningful use of certified EHR technology to avoid Medicare payment penalties.
- Meaningful use has spurred provider investment in IT systems, but exorbitant costs and ongoing interoperability issues remain.
- There is broad consensus among providers that the MU program was effective in moving providers to EHRs and to more secure, electronic exchange of patient information.
- However, compliance with Stages 1 and 2 of MU has been a heavy lift for health systems and hospitals, due in part to the short implementation timeframe and the need for dedicated staff, extensive investment in health IT systems, and process redesign.
- A 2017 study from the American Hospital Association found that the average-sized hospital spent nearly \$760,000 to meet MU administrative requirements annually.<sup>73</sup>

# TheZetemaProject

- In addition, they invested \$411,000 in related upgrades to systems during the year, over 2.9 times larger than the information technology (IT) investments made for any other domain.
- Regulatory compliance has required extensive investment in health IT systems and process redesign.
- Timelines for providers to achieve MU varied widely. Specifically, the timeline for hospitals was aggressive, while the timeline for physicians was more relaxed, and other providers, such as post-acute care (PAC) providers and the Indian Health Service, were exempt from MU entirely. Therefore, many health systems and hospitals had the capability to transmit electronic information as required under MU, but could not transmit the information to their referral partners. As a consequence of this inefficiency, as well as others, many providers felt that administrative challenges associated with MU compliance far exceeded any improvement to a patient's quality of care as a result of these activities.
- The AHA recommends that Stage 3 of Meaningful Use be cancelled and that MU requirements be streamlined and increasingly focus on interoperability, without holding providers responsible for the actions of others.

## Recent Activity

- The Trump administration and HHS have issued statements announcing their commitment to reducing regulatory burdens.<sup>74</sup>
- In April 2018, CMS issued its hospital inpatient PPS proposed rule for fiscal year 2019. The rule would increase rates by 1.75% in FY 2019 compared to FY 2018, after accounting for inflation and other adjustments required by law.<sup>75</sup>
- The proposed rule includes an initial market-basket update of 2.8% for those hospitals that were meaningful users of electronic health records in FY 2017 and that submit data on quality measures, less a productivity cut of 0.8% and an additional market-basket cut of 0.75%, as mandated by the ACA.
- CMS has renamed the EHR Incentive Programs as the “Promoting Interoperability Programs” and introduced a more flexible, performance-based approach to determining whether a hospital has met the requirements to avoid a payment penalty under Medicare. Hospitals would have to use the 2015 Edition Health IT Certification Criteria and report performance for a 90-day reporting period in both 2019 and 2020.
- CMS proposed to require that hospitals report only four electronic clinical quality measures for one quarter and reduce the number of eligible electronic clinical quality measures (eCQMs).
- The new scoring mechanism would allow hospitals to receive points on measures under four objectives – e-prescribing, health information exchange, provider-to-patient exchange, and public health and clinical data exchange. CMS proposes to retain some measures from Stage 3, modify others, and remove six measures. The agency also proposes to add two measures related to opioid treatment.

## Case Studies: Scope of Practice

### Kaiser Permanente (KP)

- KP's integrated model and team-based care has created an environment that encourages an expanded SOP for non-physician healthcare providers.<sup>76</sup>
- Provides team-based care where each team follows a group-practice model composed of 3 to 5 clinicians (physicians, NPs, or physician assistants), 2 registered nurses, 1 to 2 receptionists or clerks, and 6 to 7 registered practical nurses or medical assistants that provide care to a panel of 8,000 to 15,000 patients.<sup>77,78</sup>
- Teams have the freedom to adapt to the needs and conditions of their patient population. For instance, a team can decide to hire more or fewer physicians, non-physician clinicians, or support staff depending on the patterns of illness contracted by the population it serves.

### Minute Clinics

- A popular example of how SOP rules have been changed in order to provide patients with more affordable and convenient healthcare services<sup>79</sup>
- Clinics are run entirely by nurse practitioners who use software-based protocols to offer vaccinations and basic medical attention for a limited set of health problems.
- Proponents believe retail clinics offer a way to help reduce inappropriate use of hospital emergency rooms for basic medical services.<sup>80</sup>
  - Researchers have estimated that up to 27 percent of ED visits could have been handled appropriately at retail clinics and urgent care centers, offering cost savings of \$4.4 billion per year.<sup>81</sup>
- Retail clinics could increase total costs of care, however, for several reasons.<sup>82</sup> First, these clinics could complement physician care instead of replacing it and simply serve as a first point of contact before a patient visits a physician or ED. Second, if the care provided by retail clinics is of lower quality than that provided by doctors or hospitals, patients may require subsequent emergency care or hospitalization if they visit a clinic first instead of going directly to another source of care. Third, although retail clinics' list prices for services appear low, they may in fact be higher than the reimbursement rates negotiated between traditional providers and insurance companies. Finally, the affiliation between retail clinics and retail sites that also fill prescriptions could create a conflict of interest that promotes unnecessary prescribing

## 7.1 Provider Regulation: Discussion Questions

- To what extent is regulation a cost driver for providers?
- What are some of the most important/beneficial regulations?
- What are some of the more harmful/wasteful/unnecessary regulations?
- What are some unintended negative consequences of regulation?
- Where/how could Scope of Practice (SOP) restrictions be reduced without threatening patient safety? What would be the result of such changes?

- Should Certificate of Need (CON) laws be eliminated? Modified? How?
- Should Meaningful Use (MU) requirements be reduced and refocused on interoperability?
- Where could increased regulation benefit consumers? Providers?
- Where are opportunities to remove, reduce, or modify regulation that could save provider cost/hassle without removing important consumer protections or increasing system costs?
- What has the impact of HIPAA been, both positive and negative?
- How much of the regulatory burden providers face comes from states vs. the feds?
- Should states be required to harmonize their Essential Health Benefits regulations with federal standards?
- To what extent is bad regulation due to politics/ideology vs. poor/uninformed lawmaking?

## 8. Industry Disruptors

### Summary Table

Stakeholders/ Partners	Amazon JPMorgan Chase Berkshire Hathaway	CVS Health- Aetna Merger	Walmart- Humana Acquisition	Cigna- Express Scripts Merger	UnitedHealth Group/OptumCare Physician Practice Purchases
<b>Industry Disrupted</b>	Health insurance industry (benefits to their employees)	Insurance/ PBM	Insurance/ PBM/ Medicare Advantage/ Pharmacy/ Retail healthcare	Insurance/ PBM	Insurance/physician practice/Medicare Advantage/ outpatient care
<b>Progress</b>	Announced January 2018; Atul Gawande, MD, announced as CEO June 2018	Announced December 2017; merger review extended in May 2018 at DOJ request; combined management team announced June 2018	Speculation since March/April 2018; analysts recently predicted that the merger would not go through	S4 filed May 2018; merger review extended in May 2018 at DOJ request	Announced December 2017, this vertical merger will further increase UHG's capacity to provide ambulatory care
<b>FTC Approval</b>	N/A	<b>Pending</b>	<b>N/A</b>	<b>Pending</b>	<b>N/A</b>