



Commonwealth of Massachusetts Department of Public Health

Proposed Revision of the Determination of Need Regulation 105 CMR 100.000

August 23, 2016



Presentation Overview

- Historical Overview of Determination of Need**

- Overview of Proposed Revision of 105 CMR 100.000, *Determination of Need***

- Next Steps**

- Questions**

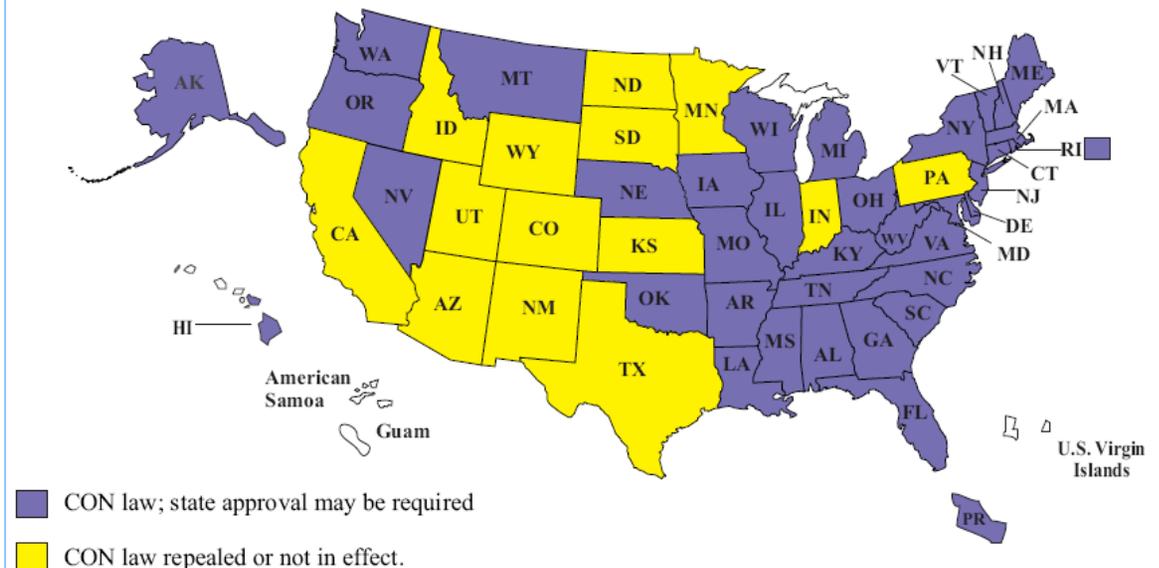


Historical Overview of Determination of Need

- ❑ Many laws originally contemplated DoN comprehensively. However, gradual deregulation resulted in many of these laws being either repealed or scaled back during the 1990s.

- ❑ Many health care experts have highlighted deregulation as contributing to escalating health care costs.
 - ✓ According to a 2006 Missouri State Senate special commission, researchers found that Massachusetts had the least expansive DoN law when compared to neighboring New England states.

State Certificate of Need (CON) Health Laws, 2013



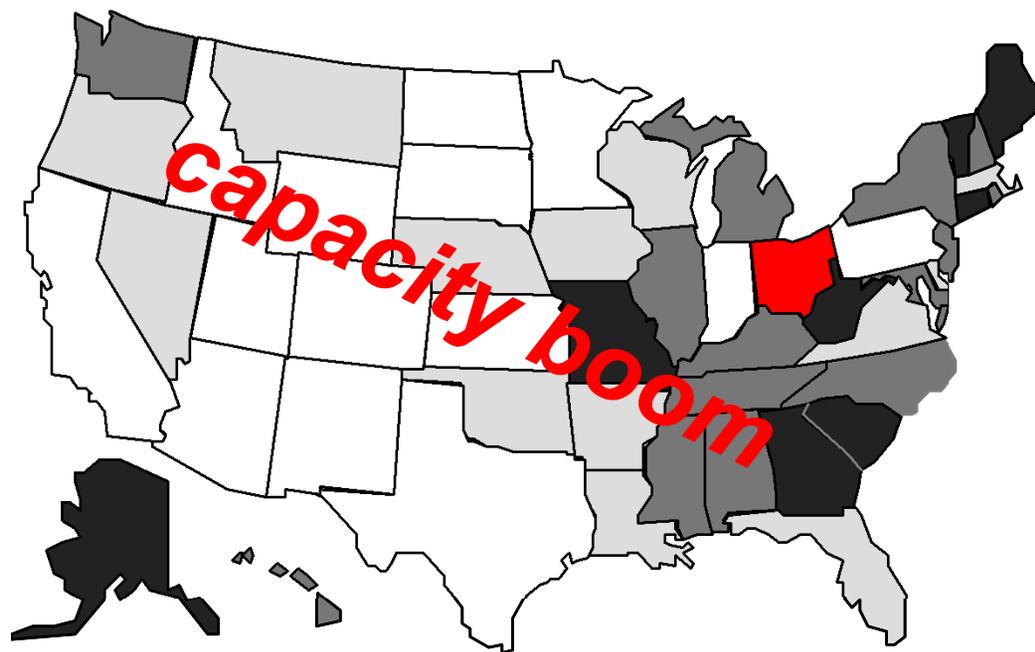
Compiled by NCSL November 2013; based on data from AHPA & State Agencies.



Historical Overview of Determination of Need

EXAMPLE 1:

In 4-years following deregulation, Ohio saw an increase in 19 new hospitals (of which 15 rehab), 137% increase in outpatient dialysis units, 280% increase in radiation therapy, 548% increase in freestanding MRIs, and a 600% increase in ambulatory surgery centers.

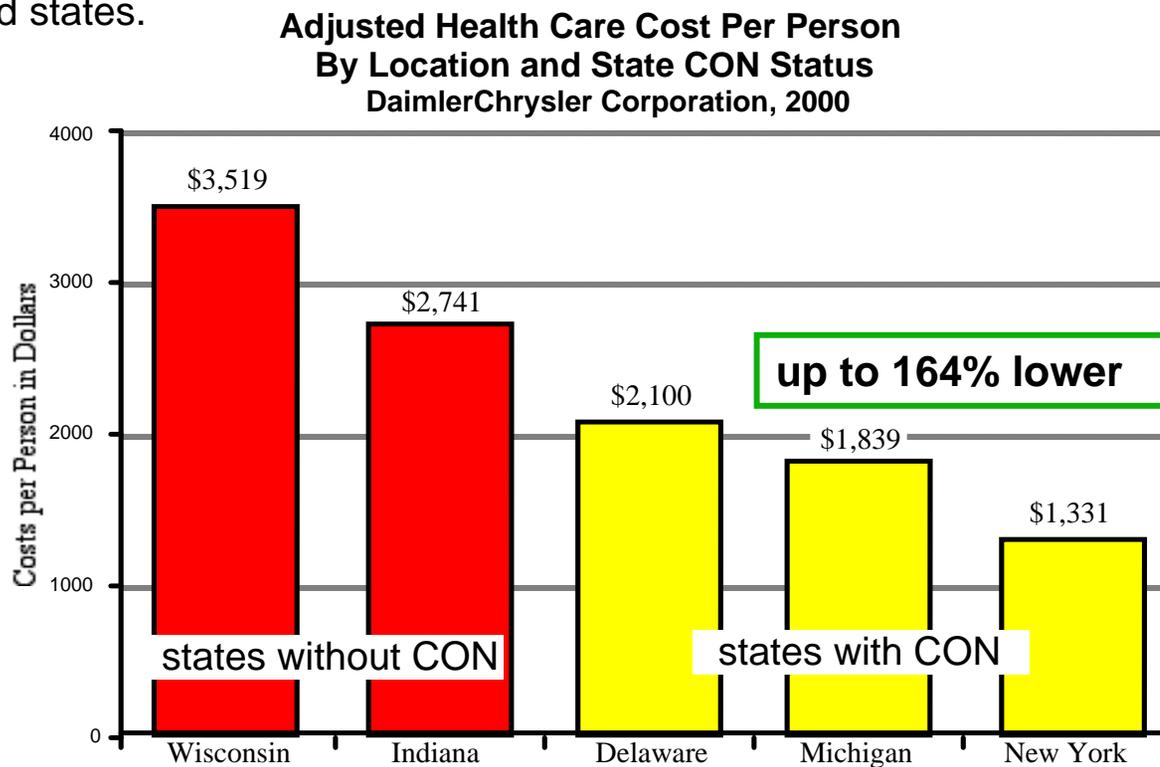




Historical Overview of Determination of Need

EXAMPLE 2:

DaimlerChrysler Corporation, GM, and Ford Motor Company completed individual business analyses to compare health care costs for their employees in DoN-regulated states vs. non-DoN-regulated states.





Historical Overview of Determination of Need

EXAMPLE 3:

Connecticut placed a moratorium on all mergers and acquisitions, calling for significant enhancements to their DON laws and regulation, citing a need to reduce costs while incentivizing market competition on the basis of value.



STATE OF CONNECTICUT
GOVERNOR DANIEL P. MALLOY

Thursday, February 25, 2016

Gov. Malloy Signs Executive Order to Create More Transparency in the Hospital Industry

Governor Dannel P. Malloy today announced that - in light of the evolving healthcare industry and continuing changes in market conditions - he has signed an executive order that will begin an extensive review of Connecticut's laws and regulations surrounding processes on the establishment, termination, transfer, acquisition, and expansion of hospitals and medical service providers.

The review is intended to ensure that consumers in Connecticut continue to receive equitable access to health care that encourages transparency and competition, provides accessible and affordable health care delivery, contributes to economic development, and promotes community benefits.

"We've been taking a piecemeal look at the Certificate of Need process for several years. It's time for comprehensive reform," Governor Malloy said. "With continuing changes in the healthcare industry, it is critical that our state laws ensure that all hospitals continue to thrive, and that the deck is not stacked in favor of fewer than a handful that dominate the marketplace. We need balance. Fewer healthcare systems mean fewer choices for consumers, and that can dramatically affect both the quality of care and costs. It's time we take a holistic look at the acquisition process."



Historical Overview of Determination of Need

- ❑ The mission of the Massachusetts Department of Public Health (DPH) is to
 - ✓ prevent illness, injury, and premature death;
 - ✓ assure access to high quality public health and health care services; and,
 - ✓ promote wellness and health equity for all people within the Commonwealth.

- ❑ This mission has historically been interpreted to direct DPH to play an active role in
 - ✓ 1) measuring population health and wellness, including identification and understanding of the underlying social determinants of health; and
 - ✓ 2) delivery system policy and design.

- ❑ Consistent with this interpretation, the Massachusetts General Court established the Determination of Need (DoN) Program within DPH in 1971.
 - ✓ Intended to provide state government with a regulatory mechanism to ensure resources were allocated so “*a minimum expectation of health care services*” would be available to all residents at the lowest reasonable aggregate cost.



Outdated and Outmoded

- ❑ **Problem Statement:** Massachusetts' DoN regulation has been outpaced by a rapidly evolving healthcare market and currently does not align with DPH's core mission.

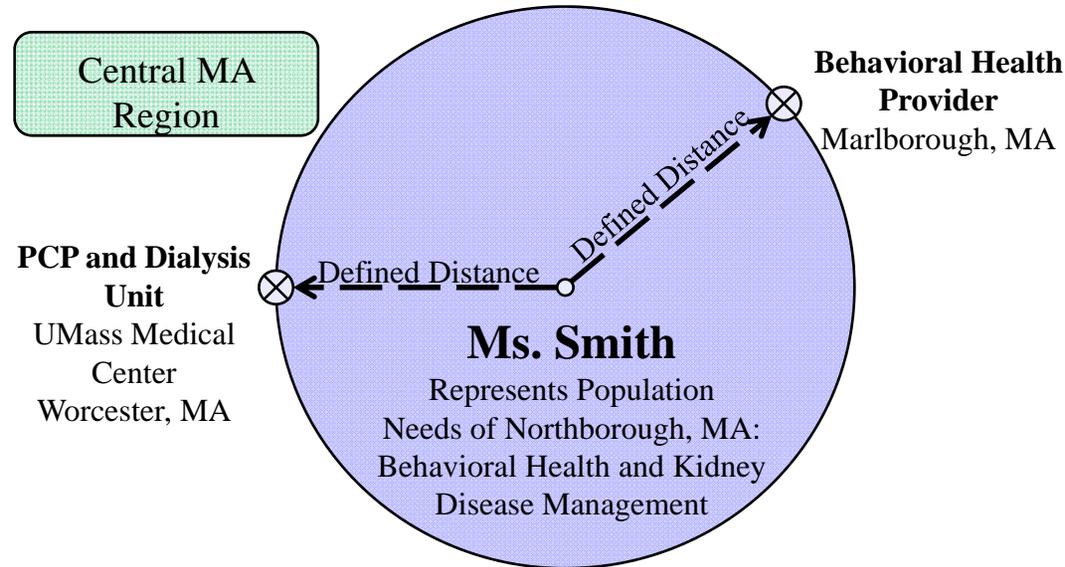
- ❑ **1971:** DoN established.
 - ✓ **Providers:** Care largely provided in standalone, not-for-profit hospitals or small group practices.
 - ✓ **Payment:** Fee-for-service or cost-based reimbursement. Rate setting commission set public rates.
 - ✓ **DON:** Played a critical role in protecting MA from state overspending on new technologies and duplicative services. Goal was to prevent saturation through non-duplication of services.

- ❑ **2016:** Post-Chapter 224 and ACA health reform.
 - ✓ **Providers:** Significant provider consolidation. Complex health systems that closely control patient referral patterns. Increased reliance on innovation through technologies and services.
 - ✓ **Payment:** Systems taking on increased risk and no government rate setting.
 - ✓ **DON:** Objective has been the non-duplication of services, rather than incentivizing competition on basis of value. Increasingly out of alignment with DPH mission (*i.e.* population health) and state goals for delivery system transformation.

- ❑ **Result:** Despite these substantial changes in health care over the past 45-years, due to regulatory stagnation, DoN has become outdated and outmoded.
 - ✓ However, DoN represents a significant executive branch tool that can be realigned to advance the state's public health and health care reform goals.



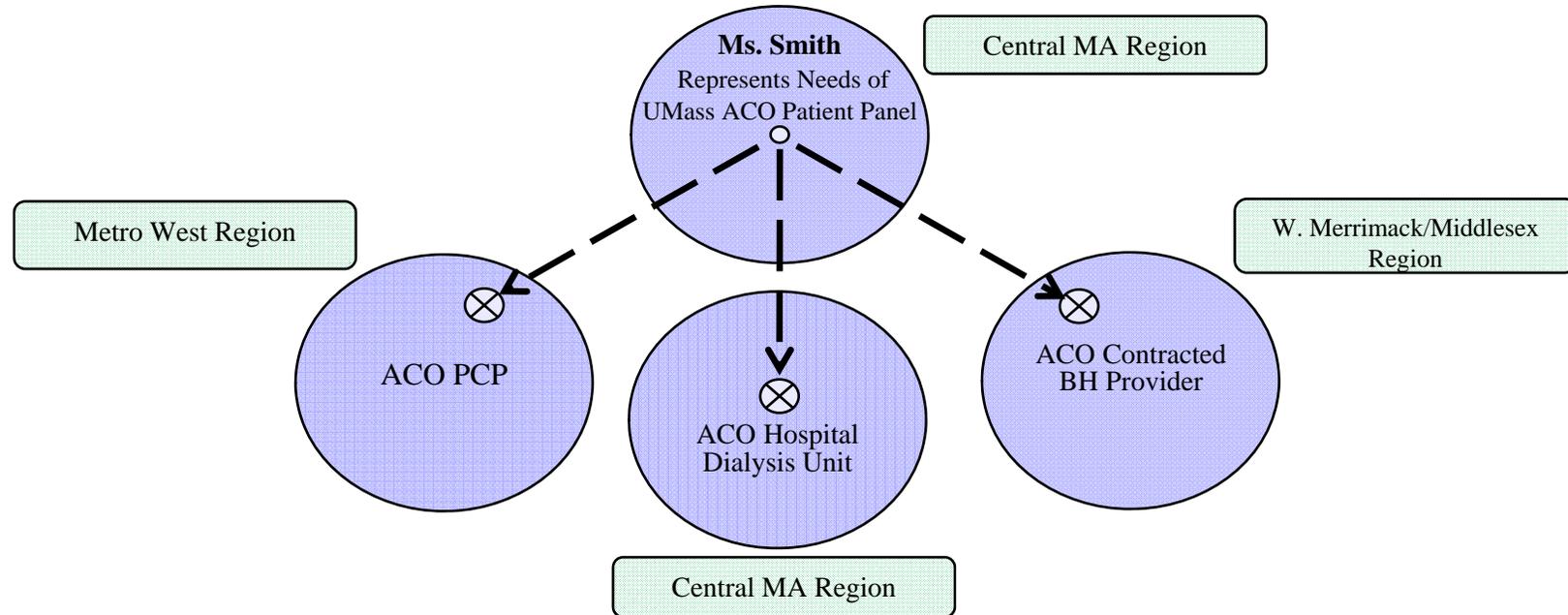
Traditional Health Planning (1970-2012)



- Map population health needs** of defined, limited geographic area
- Measure excess/scarcity** of needed services within area
- Historical role of DoN:**
 - ✓ To allow government to **monitor and control costs** of large projects and new technologies (era of rate setting and cost-based reimbursement)
 - ✓ To empower government to **regulate excess/scarcity** through geographic distribution of services



Potential ACO View of Future Role of DoN and Health Planning



- ❑ **ACO “owns” patient risk** – question for ACO is how to best manage risk by ensuring access to needed services at lowest cost
- ❑ **ACOs could argue that DoN not needed** as ACOs will be best situated – and at risk – to manage and plan for the needs of their patient panel
- ❑ **Question is access to services within the system**, not excess/scarcity within a defined geographic area

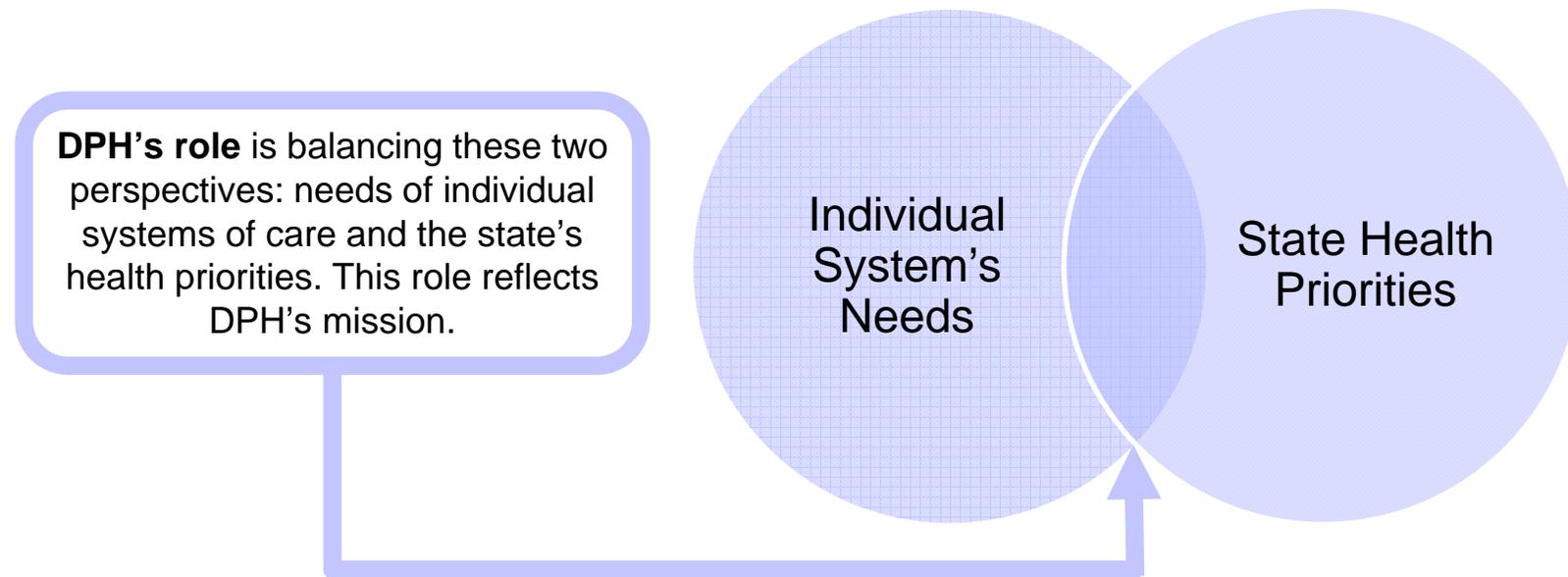


False Choice

- Neither scenario is reflective of today's health care market.**
- No health care system today represents an ACO that is fully “at-risk”** – largely definitional or currently represent payor/provider contracts with limited to no downside risk (i.e. providers not yet truly at-risk for patient panel).
- Regardless of the speed at which ACOs become the new paradigm – or whether ACOs even succeed at all – **it is clear that the market is moving towards providers taking on more risk.**
- For systems to successfully take on more risk (i.e. value-based health care), **systems will need to develop an expertise and focus on population health, *both*** at the patient panel level, as well as at the community level (e.g. understanding how mental health, substance abuse, housing, environment, and other community-level factors impact their patient panel's outcomes).
- DoN can help create capacity for systems of care to bridge to this new reality.



What is Government's Role?



- ❑ **Individual System's Needs:** Applicants can best demonstrate the *Triple Aim* (IHI model) 1) need within their system, 2) competitive price, and 3) demonstrable "public health value".
- ❑ **Health Priorities:** DPH defines "public health value," as well as work across state government to establish executive branch "Health Priorities" at state/regional level (e.g. what are the community-level/underlying causes of that provider's patient panel's health disparities).
- ❑ **DoN Role:** The question for DON becomes how proposed projects address and balance both a system's needs and health priorities.



Re-Building Today's DoN to Advance DPH's Mission

- 1) Simplify and Streamline**
- 2) Modernize to Reflect the Modern Health Care Market and Realign with DPH Core Mission**
- 3) Increase Objectivity and Transparency**
- 4) Create True Benchmarking and Accountability of DoN Projects**
- 5) Leverage CHI Investments Towards State Health Priorities**
- 6) Reframe Reviews to Non-Innovative Equipment and Technologies**
- 7) Align Incentives with Community Hospital Sustainability**



1) Simplify and Streamline

DoN Today:

- ❑ Administratively burdensome and complex with over 80-pages of regulation, 10 review factors, and confusing layout and drafting with unnecessary ambiguity;
- ❑ Different processes and carve-outs apply for different types of projects without clear purpose;
- ❑ Does not allow for DoN and Licensure processes to be concurrent;
- ❑ Only allows for applications during certain times of the year;
- ❑ Does not appropriately differentiate between proposed market expansions and often necessary deferred maintenance.

DoN Tomorrow:

- ❑ Reduces 57% or 40 pages of regulation;
- ❑ Restructures and renumbers regulation, reducing regulatory complexity and increasing usability;
- ❑ Redrafts to eliminate ambiguous wording and to afford increased clarity and accessibility;
- ❑ Significantly simplifies DoN by standardizing processes and timelines across all project categories;
- ❑ Allows applicants to seek both DoN and Licensure plan review concurrently, saving applicants significant time and costs;
- ❑ Eliminates specific filing timelines, allowing filings on a rolling basis; and,
- ❑ Creating a new "Conservation Projects" definition and expedited review process for projects that meet the expenditure minimum but, in their entirety and without disaggregation, simply maintain a building or service for its designated purpose and original functionality (e.g. new roof, painting, carpeting, electric, catch-up on deferred maintenance).



2) Modernize and Realign

DoN Today:

- ❑ Objective is the “non-duplication of services,” limiting DPH’s ability to incentivize public health-driven market competition;
- ❑ Defines “Applicant” as the individual facility;
- ❑ Focuses much of DPH’s review on cost and market questions without needed coordination with the HPC and the AGO, creating cross-agency duplication;
- ❑ Does not require applicants to show why capital projects needed by patients over less-expensive public health strategies and interventions;
- ❑ Does not require MassHealth participation;
- ❑ Asks the wrong question for mergers and acquisitions by asking: “*does this community need a hospital?*” failing to appropriately account for cost, market, or public health implications of increased consolidation.

DoN Tomorrow:

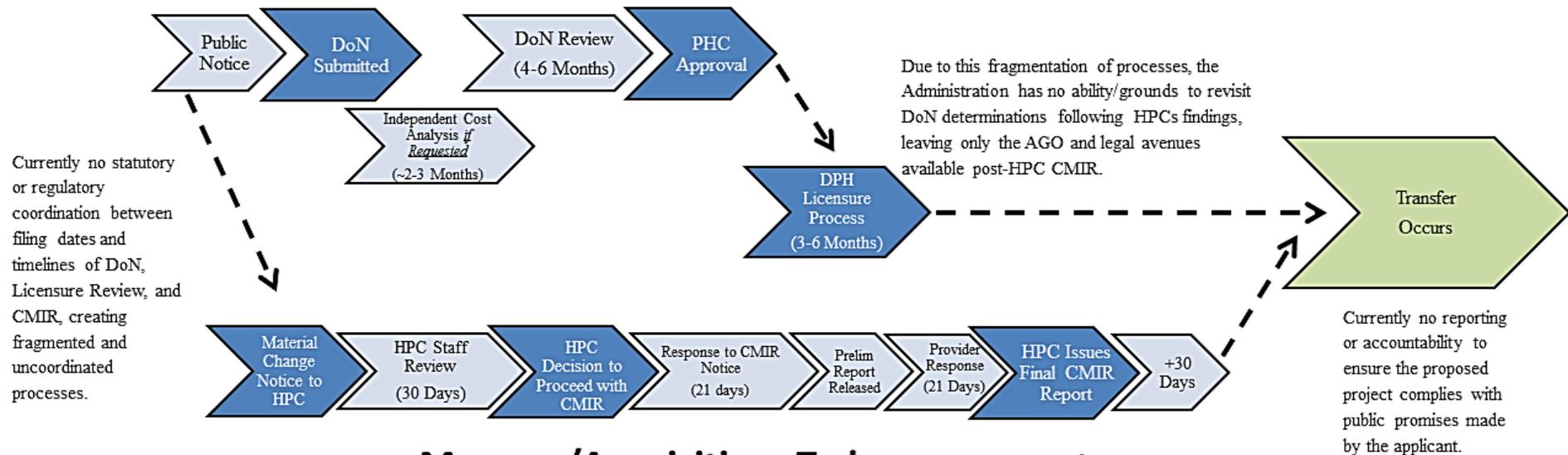
- ❑ Amends objective to better align with statute and to reframe around public health within the modern health care market;
- ❑ Defines “Applicant” as the registered provider organization;
- ❑ Refocuses DoN’s factors for review on DPH mission-centric priorities of equitable access and promotion of population health strategies;
- ❑ Requires applicants to provide evidence that on balance a project is superior to alternative evidence-based strategies and public health interventions;
- ❑ Requires MassHealth participation as a “Standard Condition” of all DoN approvals;
- ❑ Realigns review of mergers and acquisitions with DPH’s mission by asking applicants to demonstrate how the proposed merger or acquisition would add measurable public health value, while leveraging HPC’s Cost and Market Impact Analysis, ensuring critical cross-agency collaboration.



2) Modernize and Realign (Example)

DoN Example:

MERGERS/ACQUISITIONS TODAY – DON AND CMIR



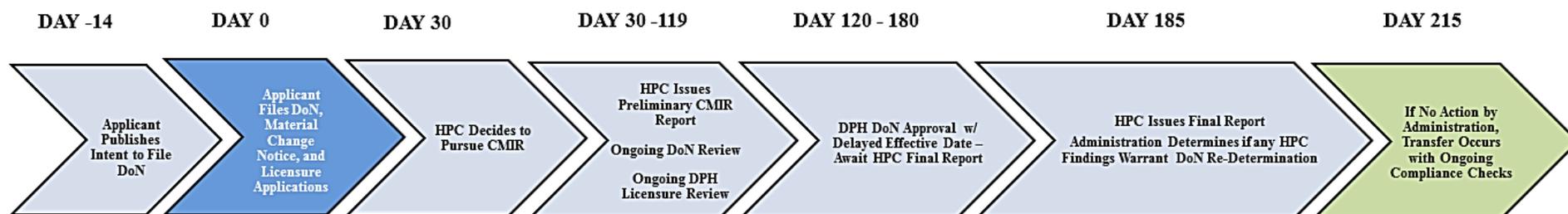
Mergers/Acquisitions Today: Fragmented, uncoordinated process that lasts up to **12 months** (DoN, CMIR, Licensure), leaving judicial system as the only option to stop a merger/acquisition.



2) Modernize and Realign (Example)

DoN Example:

MERGERS/ACQUISITIONS TOMORROW – DON AND CMIR



Mergers/Acquisitions Tomorrow:

Streamlined, coordinated process that lasts up to **8 months** (DoN, CMIR, Licensure), allowing the Administration the ability to disapprove a merger/acquisition.



3) Increase Objectivity and Transparency

DoN Today:

- Allows projects greater flexibility in meeting all factors of review on basis of mitigating attributes;
- Lacks needed clarity on disaggregation;
- Does not require DPH to publicly post project-related materials electronically;
- Limits DPH to no more than one public hearing;
- Does not specifically require sound community engagement prior to project filing.

DoN Tomorrow:

- Requires proposed projects meet all applicable factors of review;
- Explicitly bans disaggregation;
- Strengthens transparency requirements, including for DPH by requiring DPH electronically post project materials; and,
- Increases opportunities for stakeholder engagement by:
 - 1) Allowing the Commissioner to call for additional hearings, allowing for additional stakeholder feedback; and,
 - 2) Requiring sound community engagement and consultation, including engagement of community coalitions statistically representative of the Applicant's patient panel.



4) Benchmarking and Accountability

DoN Today:

- Does not require regular and public post-approval reporting;
- Approvals occur within the context of a “moment in time,” not allowing for post-approval compliance;
- Relies on licensure authority, creating an “On/Off Switch” regulatory approach.

DoN Tomorrow:

- Requires regular and public post-approval reporting to the Public Health Council (PHC);
- Allows PHC latitude to require additional contributions to Community Health Initiatives (CHI) if determined the holder has failed to meet the promises and/or measures they attested to during the approval process;
- Conditions holder's facility licenses with terms and conditions of DoN approval for a period after project completion, allowing broader range of regulatory actions, creating “dimmer switch” regulatory approach.



5) Leveraging CHI Towards State Health Priorities

DoN Today:

- ❑ No data-driven or coordinated disbursement of the more than \$170M in CHI investments committed between FY06 through FY17 to-date;
- ❑ Funds not documented to ensure spending directly contributes to increased health outcomes and lowered THCE;
- ❑ Not publicly planned or competitively procured with unclear DPH role;
- ❑ Flexible community engagement standards;
- ❑ Often small, uncoordinated investments across many issue areas;
- ❑ Does not fully leveraged DPH's ability to build population health expertise across health care system, failing to incentivize providers adoption of population health strategies *both* at the patient panel level and community level needed in order to take on desired risk.

DoN Tomorrow:

- ❑ Standardizes CHI investments with enhanced coordination, accountability, and reporting, ensuring critical dollars are contributing to the improvement of community health;
- ❑ Strong community involvement with funds disbursed through a transparent process from provider organizations with final DPH approval;
- ❑ Clear community engagement expectations that set "gold standard" for community-based planning;
- ❑ Larger and/or coordinated approaches to CHI investments that ensures targeted investments with high-value returns across a community;
- ❑ Establishes a public health framework that will allow DPH to support a social determinant of health and health equity approach to community health investments. This approach will balance investments in both state "Health Priorities" as well as targeting resources towards responding to individual Community Health Needs Assessments and identified local health disparities.



6) Reframe Reviews on Non-Innovative Equipment and Technologies

DoN Today:

- ❑ Provides broad oversight of any technology or service that DPH deems as “new or innovative”;
- ❑ List last comprehensively reviewed in 1990s;
- ❑ Does not have a predictable stakeholder-involved process for review/feedback established;
- ❑ Does not take into account whether or not proposed equipment or services add value or return on investment to the health care system (i.e. are they in fact “innovative”);
- ❑ Fails to appropriately deliver this important distinction between true innovation and high-cost, high-volume revenue drivers;
- ❑ Approach at odds with need for true innovation to further patient health and drive successful cost containment.

DoN Tomorrow:

- ❑ Maintains broad oversight, but reframes by ensuring limited health care dollars are not spent on equipment and services which have evidence to be significant cost drivers with little or no documented return on investment (i.e. are not innovative);
- ❑ Ensures annual review with stakeholder input/feedback;
- ❑ Strikes the appropriate balance of incentivizing competition on the basis of advancing IHI's *Triple Aim* through innovation and cost containment, while limiting market saturation of low-value services.



7) Align Incentives with Sustainability of High-Value Providers

DoN Today:

- ❑ Current DoN places too much emphasis on non-duplication of services and individual facility cost efficiency, disadvantaging community hospitals looking to compete on value;
- ❑ Does not differentiate from deferred maintenance and major capital expansions, creating regulatory hurdles for maintaining outdated facilities;
- ❑ Historic DoN policies on ambulatory surgery cited as a contributing factor to today's market imbalance among provider types**. According to studies, these policies have contributed to hospital instability without accounting for current patient need.

DoN Tomorrow:

- ❑ Emphasis placed on a provider organization's ability to:
 - ✓ Compete on the basis of high-value care (high quality/low cost), including price;
 - ✓ Offer public health value;
 - ✓ Participate in meaningful community engagement;
 - ✓ Employ population health strategies.
- ❑ Creates "Conservation Projects" definition;
- ❑ Consistent with HPC's expert recommendations**, allows for controlled expansion of freestanding ambulatory surgery by existing hospitals or joint ventures with existing hospitals, improving hospital sustainability, while ensuring growth in low-cost settings without impacts to quality of care.



Summary

- ❑ **Significantly streamlines and simplifies DoN regulations**, reduces administrative burdens, makes common-sense reforms, and enhances cross-agency collaboration and coordination;
- ❑ **Modernizes DoN** to reflect today's health care market by incentivizing value-based, population health-driven competition;
- ❑ **Increases transparency and objectivity** by insisting on real community engagement;
- ❑ **Adds true accountability** by requiring post-approval reporting on public promises made by DoN applicants;
- ❑ **Aligns community investments with actual data-driven needs**;
- ❑ **Levels the playing field**, supporting critical community assets;
- ❑ **Meaningfully infuses public health into DoN**, supporting successful health care reform and provider transitions to greater risk.



Next Steps and Timeline

Regulations

- August 23 - October 7, 2016:** Public Written Comment Period
- September 21, 2016:** Public Hearing, 1:30PM (Boston, MA)
- September 26, 2016:** Public Hearing, 1:00PM (Northampton, MA)
- Expected Winter 2016/17:** DPH to come back before PHC to review public comments and request approval of proposed amendments, as well as accompanying sub-regulatory guidelines. Following final approval, the revised regulation will be filed with the Secretary of State.

Sub-Regulations

- CHI/Health Priorities:** DPH to convene public listening sessions across the state in order to engage in community-level discussions. Sessions expected October 2016.
- DoN-Required Equipment/Services:** DPH to host public listening sessions and expert panels on the development of sub-regulatory guidance. Sessions expected October/November 2016.



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Questions?