Washington Certificate of Need (CN) Summary of Findings

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Agenda

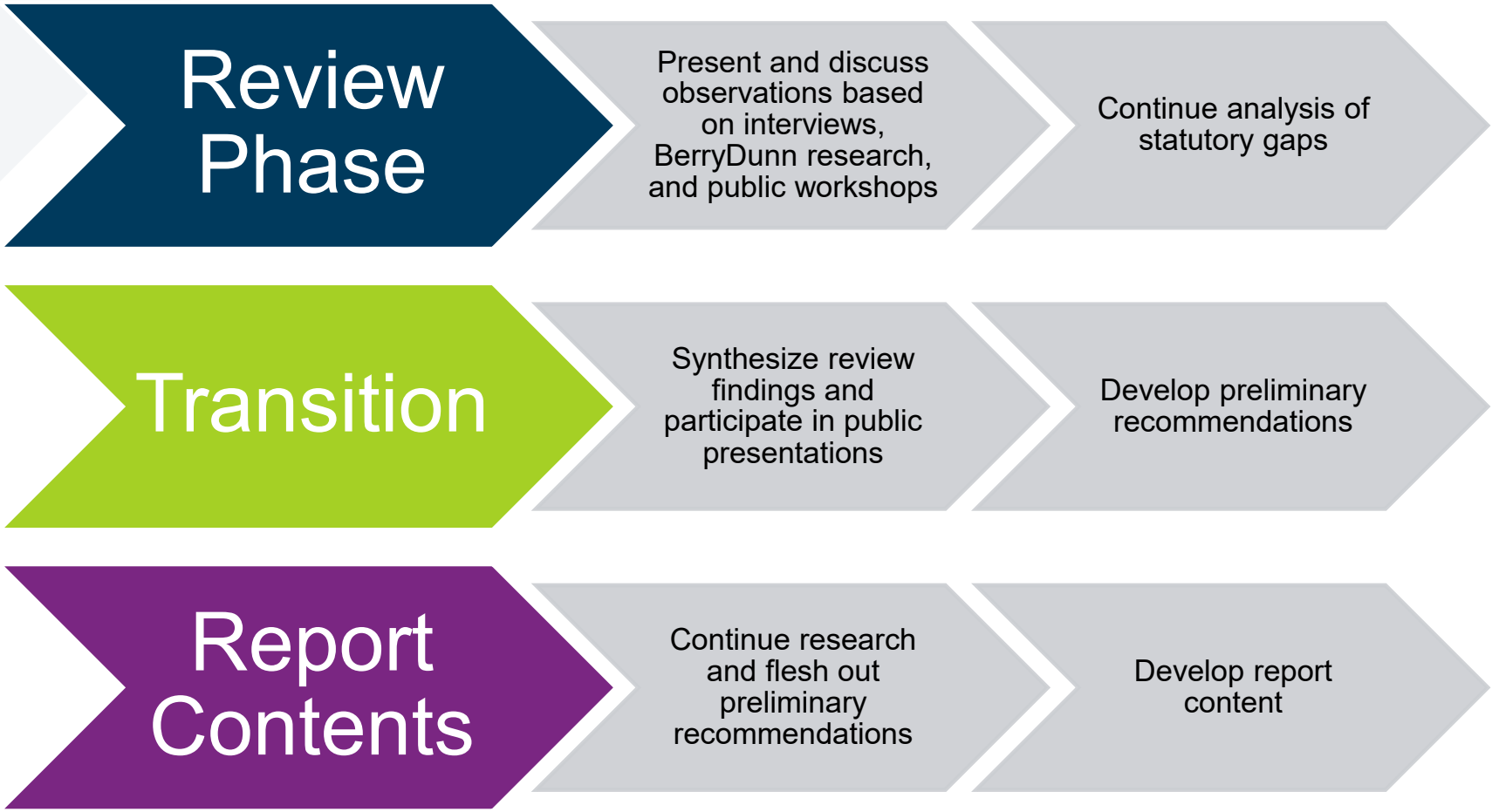
1. Introduction
2. WA and Other State Approaches to Certificate of Need
3. Equity in Access to Healthcare Services
4. Access to Care
5. Data Resources and Gaps
6. Cost of Health Services
7. Preliminary Findings

1

Introduction

Introduction

Project Approach



Statutory Gaps

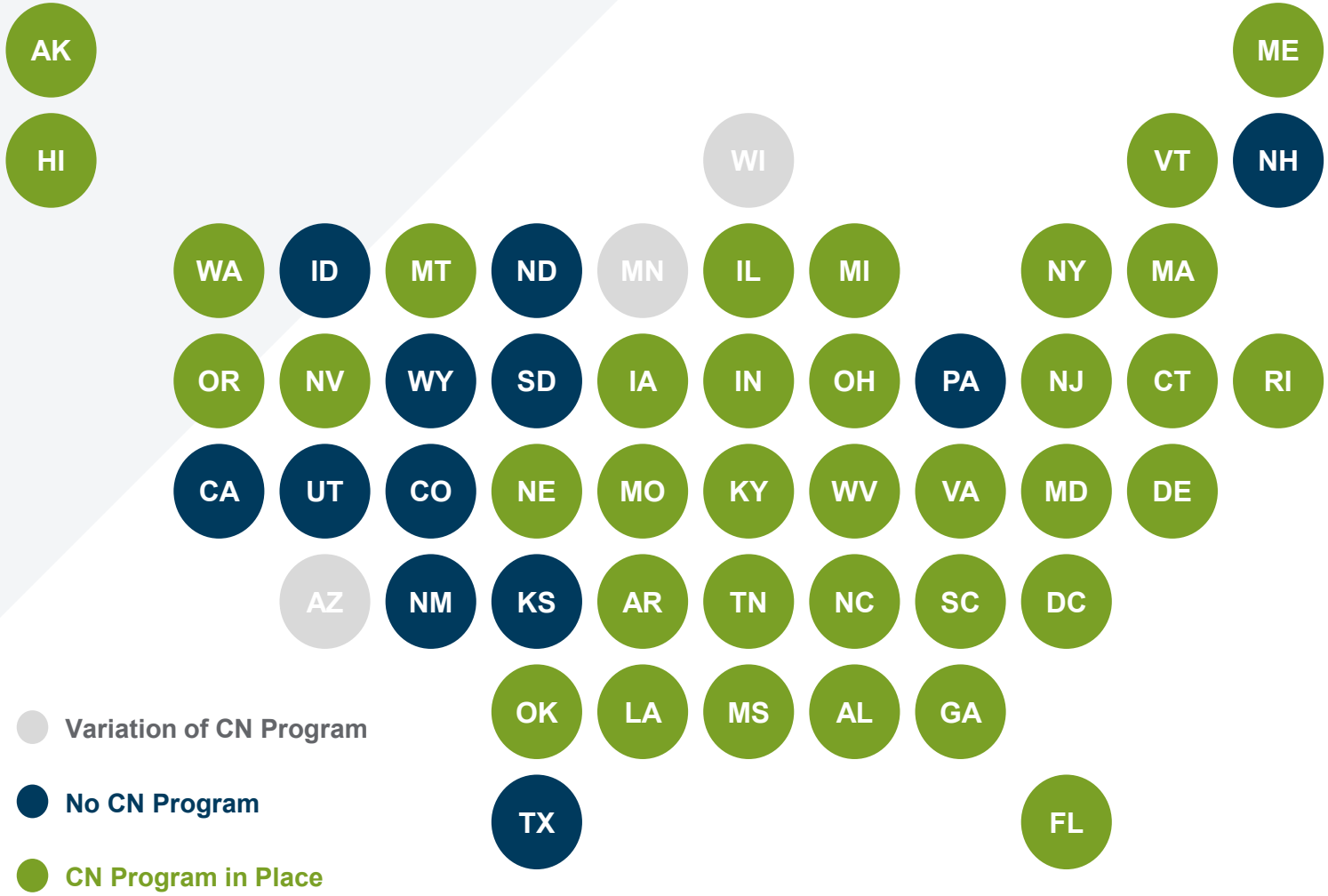
Provisions That Could be Considered Missing for the CN Program

- Statutory CN purpose
- Existence of a public planning body that represents diverse interests and expertise
- Authority of a public body to make regulatory decisions without substantial risk of litigation
- Direction for access to varied health planning expertise
- Authority, expertise, and resources to monitor compliance
- Practical and applied definition of reasonable access to healthcare services
- Regulatory discretion to offer flexibility around CN requirements
- A stable funding mechanism that does not discourage important projects
- Opportunities to address healthcare provider commercial payer price inflation

2

WA and Other State Approaches to Certificate of Need

General State Themes



36 states (including D.C.) have a CN program, and 15 states do not

CN programs vary greatly state to state

State health planning agencies and supports vary state to state

Some states utilize CN as part of a larger state health strategy

Source: NCSL Certificate of Need State Laws

State CN Requirement Comparison

Highlights

Almost all states with a CN program require entities to obtain a CN before making a significant capital expenditure

Most states require a CN for changing the bed capacity of a facility

Several states require entities to obtain a CN before acquiring major medical equipment

A few states require free-standing emergency departments to obtain a CN; Washington does not

Various types of health equity-related components are part of the CN application process in several states

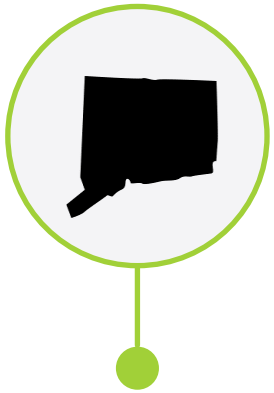
Several states require a CN before establishing an outpatient clinic

High-Level Findings From Selected States

States are guided by program goals, statutory flexibility, and population needs

Massachusetts

- Robust health planning and collaboration between several committees and state agencies
- Applicant bears burden of proof for Determination of Need (DoN) criteria
- Applicant must demonstrate that the project will compete based on price, costs, and other measures of healthcare spending
- Community Health Initiatives (CHIs)



Connecticut

- Applicant bears burden of proof for CN criteria
- Office of Health Strategy (OHS) must maintain an inventory of all healthcare facilities, equipment, and services
- Mandated biennial statewide healthcare facility utilization study

Vermont

- Applicant bears burden of proof for CN criteria
- Green Mountain Care Board (GMCB) has expansive authority over CN and overall healthcare financing
- All appeals must go directly to the state Supreme Court, resulting in very low litigation rates/costs

Hawaii

- Applicant bears burden of proof for CN criteria
- HI requires CN for both expanding services and reducing or eliminating services
- HI prioritizes non-profit hospitals and thinks CN might be the best way to discourage for-profit interests

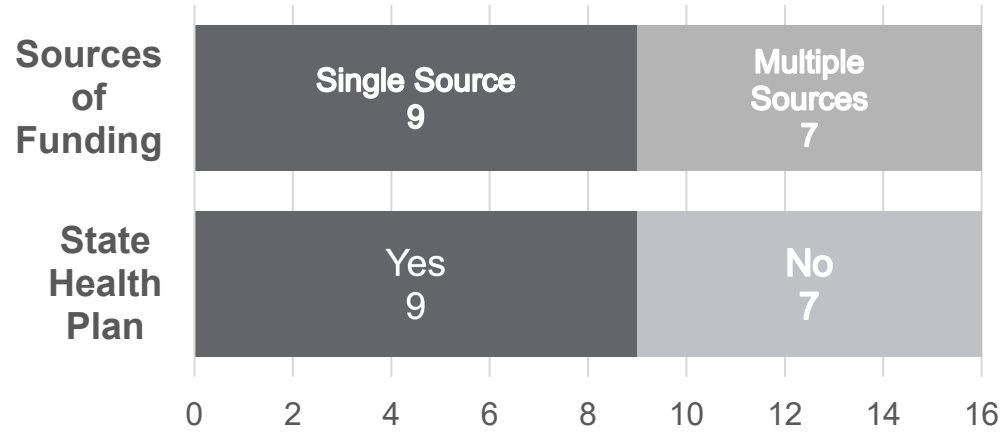
Rural Healthcare Considerations

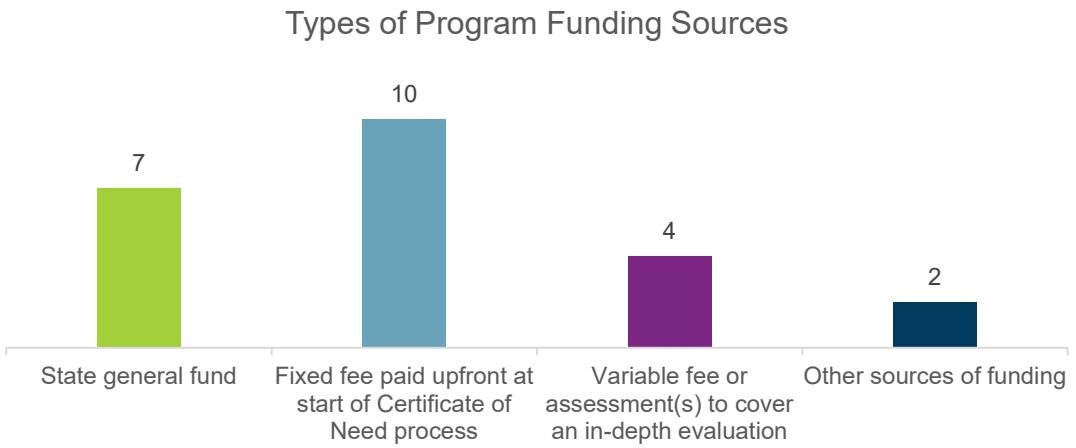
- Limited ability to:
  - Recruit staff and offer a full range of healthcare services
  - Purchase materials, supplies, and pharmaceuticals at the lower prices obtained by large systems
  - Raise capital
- Typically higher rates of uninsured, Medicare, and Medicaid patients
  - Populations with substantial healthcare needs
- Geographic coverage may not be a priority for commercial insurance carriers

CN Survey Responses

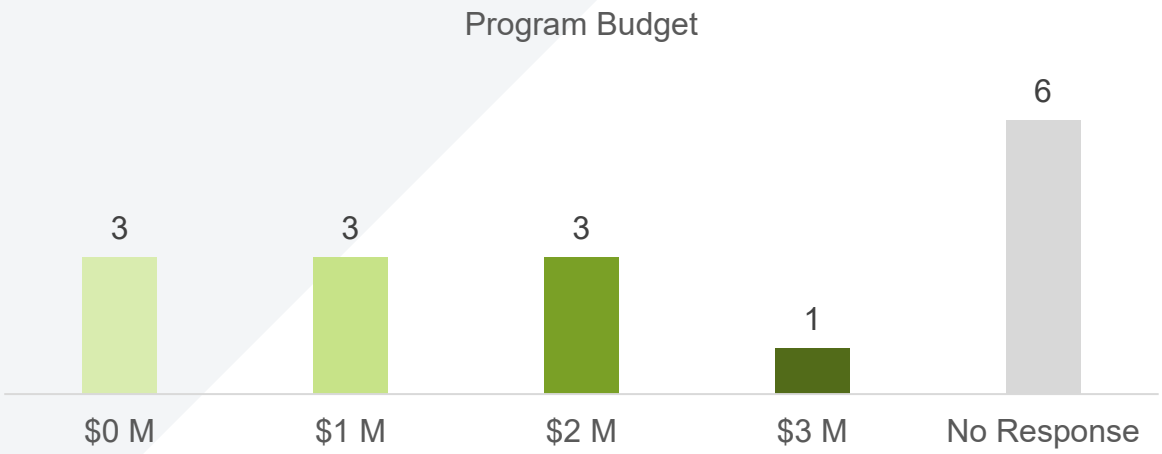
16 total respondents out of 35

- 7 of 16 respondents use multiple funding sources; 9 have a single funding source
  - Other sources of funding (2)
    - Application fee based on percentage of capital expenditures
    - Annual assessment of hospitals
- 7 of 16 respondents do not have a state health plan, 9 have a plan
  - Updates are every 1 – 5 years and vary by state

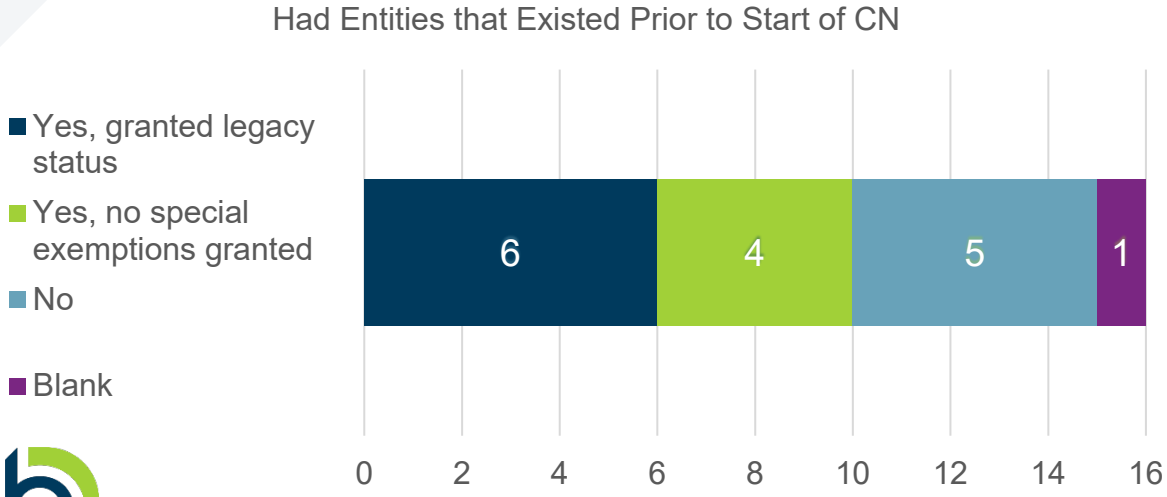




CN Survey Responses (Cont.)



- 10 of 16 responded with information about their budget, with $1M being the average answer (ranged from $0 – $3M)



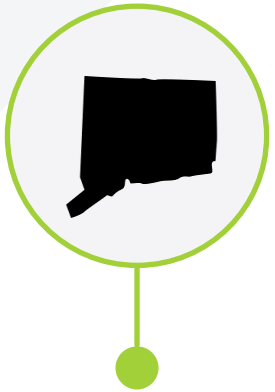
- 10 of 16 respondents confirmed they had entities that existed prior to the start of CN
  - 6 of 10 reported granting legacy status to existing entities

Certificate of Need Funding Sources

Selected State Details

Alabama

- Alabama is primarily funded through application fees with some support from the general fund
- Agency can set fee amounts and draw from the general fund when costs exceed what is collected

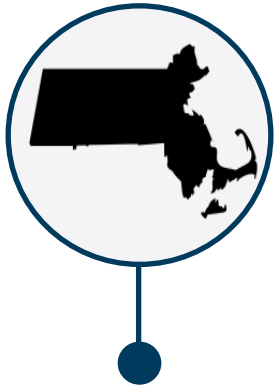


Connecticut

- Connecticut is funded through:
  - Application fees
  - State general fund

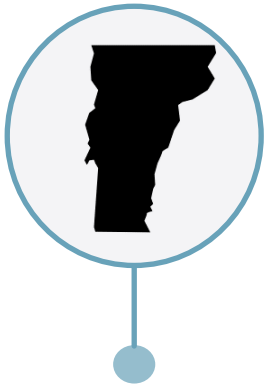
Hawaii

- Hawaii is funded from the general fund and a special fund supported by application fees
- Agency has received an All-Payer Health Equity Approaches and Development (AHEAD) Model grant



Massachusetts

- Massachusetts is primarily funded through application fees
- To provide stability to the program, expenses can be covered by the general fund when application numbers are low



Vermont

- Vermont receives funding through application fees, which are combined with the Green Mountain Care Board (GMCB) resources
- The GMCB oversees CN, so this creates multiple sources of funding for CN oversight and activities
- The GMCB is funded by State monies (40%), hospitals (30%), health insurance companies (24%), and accountable care organizations (6%)
- The GMCB has authority to contract with consultants and bill applicants for the services

Health Planning Boards/Entities

Alabama

- The State Health Planning and Development Agency (SHPDA) oversees the administration of the CN program.
- The Certificate of Need Review Board (CONRB) reviews and issues decisions on CN applications.
- The Statewide Health Coordinating Council (SHCC) is responsible for health planning in the state, including the State Health Plan (SHP).

Connecticut

- The Health Systems Planning Unit (HSP) within the Office of Health Strategy (OHS) is responsible for reviewing and issuing decisions on CN applications, as well as developing and updating the SHP.

Hawaii

- The SHPDA is responsible for administering the CN program, facilitating the development of the SHP, and issuing final decisions on CN applications.
- The SHCC advises the SHPDA, reviews CN applications, selects members of the CN Review Panel, and prepares the SHP.
- Subarea Health Planning Councils (SACs) also review CN applications as well as make health planning recommendations for their subareas.

Massachusetts

- The Public Health Council (PHC) is responsible for issuing DoN application decisions.
- The Health Planning Council (HPC) develops the SHP.
- The HPC Advisory Committee advises the HPC by reviewing drafts and providing recommendations during the development of the SHP.

New York

- The Public Health and Health Planning Council (PHHPC) reviews and issues decisions for CN applications.
- The PHHPC also oversees public health regulations among other duties.

Vermont

- The GMCB is the health care governing body for the state and its responsibilities include reviewing and issuing decisions on CN applications.
- The GMCB also updates the state health plan, Health Resources Allocation Plan (HRAP), oversees health care payment and delivery system reforms, sets reimbursement rates, and reviews and establishes hospital budgets, among other duties.

3

Equity in Access to Healthcare Services

Health Equity Definitions

CDC Definition:	WHO Definition:	WA Definition:
Fair and just opportunity for everyone to attain their highest level of health. Requires addressing historical and contemporary injustices, overcoming economic and social obstacles, and eliminating preventable health disparities.	Absence of unfair, avoidable differences among groups. Health equity is achieved when everyone can attain their full potential for health and well-being. Determined by social, economic, and environmental conditions.	Opportunity to achieve full health potential, regardless of various socioeconomic factors. Health inequities are systematic, avoidable, unfair, and unjust differences in health outcomes.

How CN Impacts Health Equity – Themes From Literature Review

Positive Impacts

Access to Care for Disadvantaged Populations: CN may protect hospitals serving high volumes of Medicaid and underserved populations

Healthcare Planning: CN may help promote geographic and economic access to healthcare facilities

Lower Social Costs: CN may help improve resource allocation

Negative Impacts

Reduced Access to Care: Research suggests CN laws can limit the establishment of new facilities and acquisition of advanced medical equipment, which can increase travel and wait times

Quality of Care: Research suggests CN laws may contribute to higher mortality rates and potentially lower hospital quality due to limited competition

Economic Barriers: Research suggests CN regulations may prevent new healthcare providers from entering the market, limiting service availability in underserved areas

Sources: NCSL, Connover & Bailey 2020

Strategies Used by Other States for Improving CN's Impact on Equity

- **Incentivizing Equity-Focused Projects:**
  - Massachusetts generally requires projects to allocate 1-5% of the total project cost toward CHIs
  - New York includes Health Equity Impact Assessments (HEIAs) for certain facilities, with requirements to evaluate the impact of their projects in the community, with a focus on medically underserved groups
    - Includes assessing changes to access, equity, disparities, and engages community members
- **Varied Application Fee Structure:**
  - A fee structure that differs based on the project cost
    - Example: MA has set $500, or 0.2% of proposed project, whichever is greater

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4

Access to Care

Impact of CN Programs on Access to Care

Dimensions of Access

Geographic Access

- Proximity to services
- Rural versus urban
- Geography features

Financial Access

- Affordability
- Coverage of services by insurance
- Insured versus uninsured

Timely Access

- Wait times
- Availability of services

Equitable Access

- Language barriers
- Transit barriers

Technology Access

- Internet/computer access
- Computer literacy for telehealth

Regulatory and Policy Access

- Licensing
- Provider network
- Healthcare laws/coverage requirements

Emergency Access

- Emergency facility and equipment
- Availability 24/7

Provider Access

- # of people per provider
- Provider skill level

Impact of CN Programs on Access to Care Summary

Positive Impacts

- Reduces provider overcapacity and the incentives to drive expensive and unnecessary healthcare services
- Provides a legal form of market allocation and improves likelihood of sustainable provider business models
  - May offer a more efficient use of available workforce
- Requires a public process for scrutinizing questionable provider investments
- Improves transparency of health system planning issues and opportunities, especially in rural communities

Impact of CN Programs on Access to Care Summary

Negative Impacts

- Application fees and the CN administrative requirements may discourage provider investment
- Need determination formulas may not accurately reflect current healthcare dynamics, particularly in rural areas
- Potential public perception that CN is unnecessary and results in unmet healthcare needs
- Provider market protection without additional transparency may result in higher commercial payer prices, creating an affordability barrier to access

Certificate of Need and Analyzing Access

Considering Commercial Insurance Company Provider Network Adequacy Requirements

Certificate of Need

- County-level approach to determine geographic needs
- May include quantitative requirements that do not adequately reflect current healthcare trends
- Does not adequately consider population centers, transportation routes, or natural geographic barriers
- May reflect political and regional government preferences

Provider Network Adequacy and Time/Distance Standards

- May include quantitative or qualitative measures associated with reasonable access
- Many states rely on federal time and distance standards between populations and healthcare provider types
- County lines are largely irrelevant
- Sophisticated tools exist for measuring compliance with time and distance thresholds

5

Data Resources Available and Gaps

The CN Program Can Use Available Data to Facilitate Program Goals

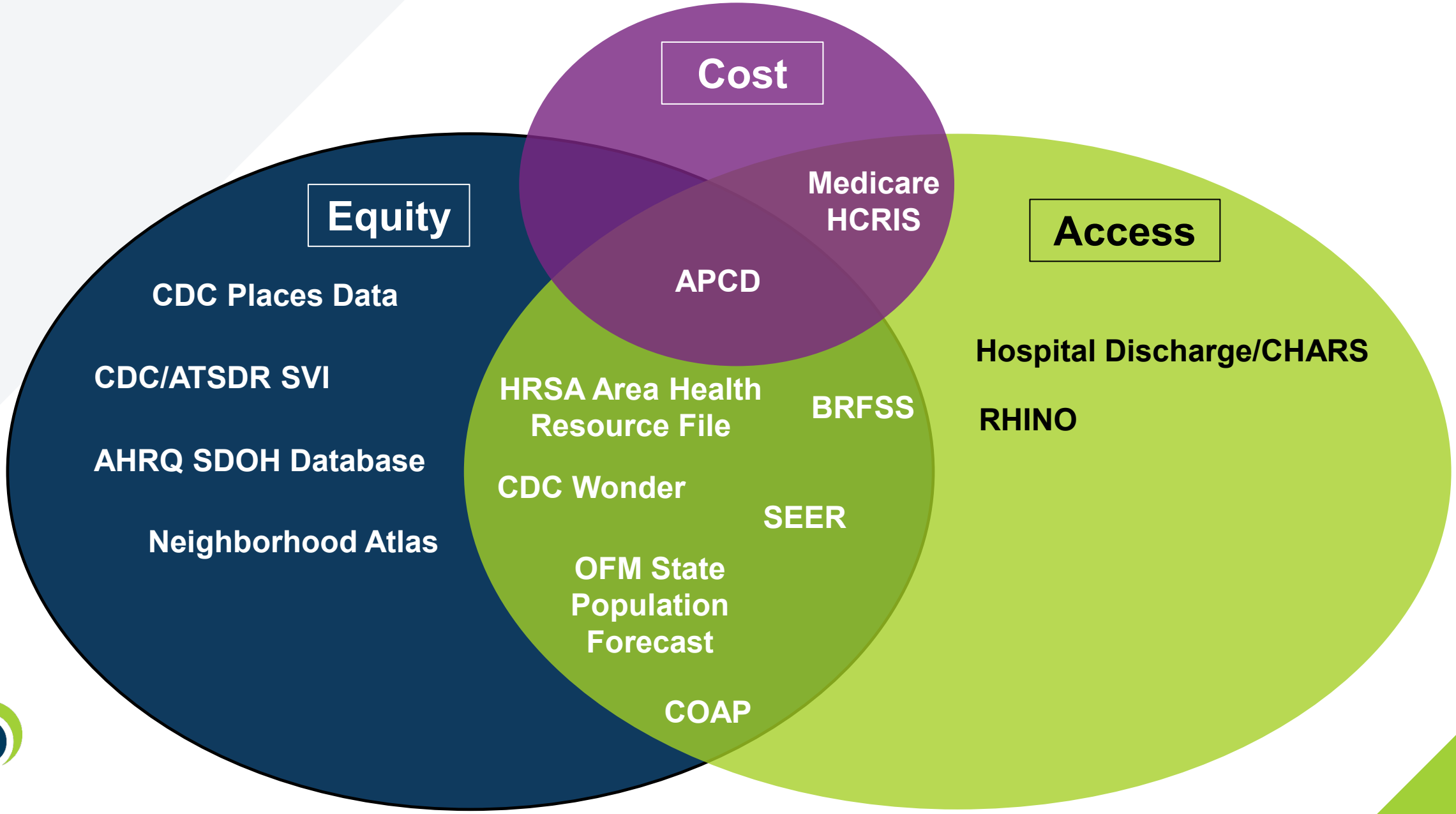
Program Goals Include:

- Promoting, maintaining, and assuring the health of all citizens in the state
- Providing accessible health services, health workforce, health facilities, other resources while controlling increases in costs
- In essence: Access, Quality, Cost Control, and Equity

Current Approaches:

- Utilization data
- County-level data
- These sources tell part of the story, but additional data sources exist

Available Data to Facilitate CN Program Goals



Direct Access to Analytic Staff Resources

- Statutorily directed analytic resources for gathering and analyzing data
- Insufficient analytic resources for comprehensive data gathering and analysis
- Dependent on information supplied by applicants or external published reports
- Reliance on volunteers and other agencies for assistance
- CN program is challenged to independently assess the necessity and potential impact of CN projects, affecting the accuracy and effectiveness of evaluations and decision-making

6

Cost of Health Services

Cost Control of Health Services

CN Impacts on Spending (Costs)

- **Prices**
  - 60+% of studies find higher commercial prices, 5% – 10% lower, and 30+% no change
- **Utilization**
  - 30% of studies find a reduction in health service use, 15% an increase, and 55% no change
- **Total or Per Capita Medical Spending**
  - 45% – 50% of studies find higher spending, 15% lower, and 40% no change

- **Regulatory Costs**
  - Staffing burden (i.e., salaries, benefits) to design, implement, and enforce CN are a small % of total CN spending impacts (0.5%)
- **Efficiency**
  - 40% of studies find worse efficiency, 40% greater efficiency, and 20% no change

1. Mitchell, M. (2024). Certificate-of-Need laws in healthcare: A comprehensive review of the literature. Southern Economic Journal, 1-38.
2. Conover CJ, Bailey J. Certificate of need laws: a systematic review and cost-effectiveness analysis. BMC Health Serv Res. 2020 Aug 14;20(1):748
3. Bailey, J. (2018). Can Health Spending be Reined in Through Supply Constraints? An Evaluation of Certificate-of-Need Laws. Working Paper.
4. Mitchell, M. (2016). Do Certificate-of-Need Laws Limit Spending? Mercatus Working Paper.
5. Ho V. Revisiting States' Experience With Certificate of Need. JAMA. 2020;324(20):2033–2035.

Price of Health Services

Spending Drivers

- Prices rise in markets where payment rates to providers are variable
  - Traditional Medicare/Medicaid = ~ Fixed
  - Private Medicare/Medicaid = Variable
  - Commercial = Variable
- Prices rise in markets where provider negotiating power over payers is greater
  - Commercial prices for hospital and physician services ~1.5 – 4x higher than Medicare
  - CN programs can restrict supply (competitiveness), adding to provider market power with payers

- Increased spending based on prices can be passed on to consumers via:
  - Higher insurance premiums
  - Higher cost-sharing (co-pays, co-insurance, deductibles)
  - Taxes
  - Other out-of-pocket costs

7

Preliminary Findings

Preliminary Findings

- Development of a CN purpose
- Creation of a board/planning entity
- Statutory provisions to address inequities
- Alternatives for measuring access
- Stability with CN program funding
- Closing data gaps
- Flexibility
- Burden of proof for need
- Coordinated approaches to consider commercial payer prices

Develop a Statutory Purpose Specific to Certificate of Need

- Help prevent excess capacity of expensive healthcare services
- Limit supplier-induced demand for unnecessary services
- Enable a legal form of market allocation and market protection to improve healthcare access in rural areas
- Potentially provide opportunities for proactive applications and ongoing review of health system efficiency
- Provide legislative direction for rulemaking and prioritize efficient use of CN program resources
- Allow CN to recognize competitive services and markets that—with reduced CN regulatory oversight—can function effectively based on cost, access, and quality

Creation of a Board/Planning Entity and Expectation for Interagency Coordination

- Represent diverse interests
- Include broad expertise
  - Ability to use subcommittees
- Provide varied perspectives
  - Geographic
  - Demographic
- Provide leadership for use and application of available data
- Potentially create a more proactive approach to planning
- Exist as a public body with clear authority to make regulatory decisions without substantial risk of litigation

Add Statutory Provisions to Address Inequities – Example NY

- Use a HEIA as part of CN applications
  - Encourage facility projects to consider community impacts, particularly for medically underserved groups
  - Include opportunity for community input
  - Existing HEIAs in NY apply to a subset of facility types:
    - General hospitals
    - Nursing homes
    - Diagnostic and treatment centers that meet certain criteria
    - Midwifery birth centers
    - Ambulatory surgery centers

Statutory Provisions to Address Inequities – Example MA

Incorporates CHIs and social determinants of health (SDOH)

- 1-5% of funding allocated

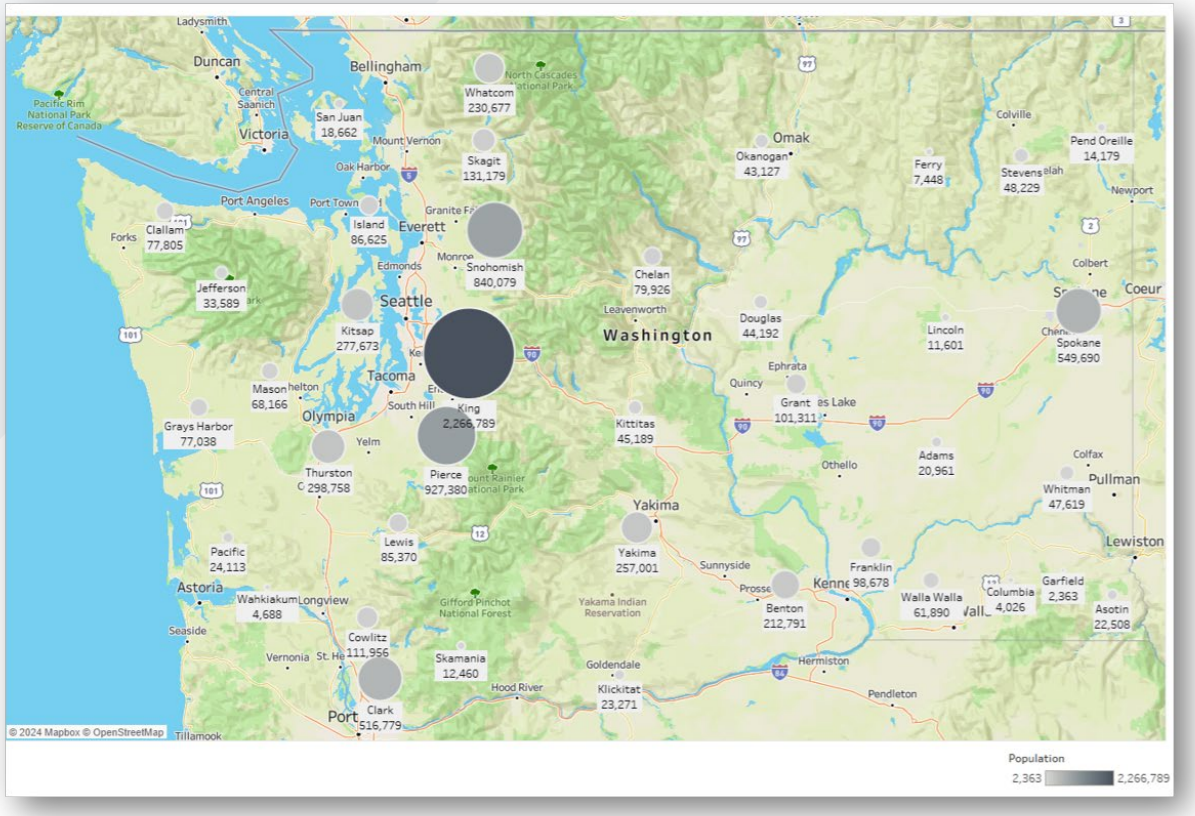
MA – Identifies six common SDOH focus areas:

- Social environment
- Built environment
- Housing
- Violence and trauma
- Employment
- Education

Enhanced Statutory Provisions for Considering Access

Washington Population

2022 U.S. Census Bureau Data June 22, 2023



- Evaluate access at the county level and incorporate time and distance
  - Recognize local resources available in communities
  - Consider access to providers across state and county lines
  - Seek synergies with commercial insurance payer network adequacy standards

Improve Stability of CN Funding Streams

Consider approaches used in other states

- Washington unique with sole reliance on application fees
- Entities not actively applying for CN benefit from the CN market protections
- Applications vary in complexity and other states allow use of outside expertise at the applicant's expense

Closing Data Gaps

Statutory changes helpful to address current limitations:

- Insufficient resources dedicated to data analysis in support of CN
- Direction for use of all state resources
- Reliance on information supplied by applicants or external reports
- Dependence on volunteers and other agencies for assistance
- Public process for accountability and use of available data

Flexibility

Offer Flexibility From State Health Plan Model

- Waive/exempt specific CN requirements
- Allow for a continuous feedback and review process
- Encourage investment in underserved communities
- Avoid dependency on planning models that may not be current

Proof for Need

Assign Primary Burden of Proof for Need to Applicant for Demonstrating

- Quantitative and qualitative evidence
- Expertise within specific communities
- Innovative approaches to care delivery to be considered and incorporated into health planning

Support Opportunities to Address Commercial Payer Prices

Designated expertise to understand healthcare provider commercial payer price pressures

Recognize the market protection that CN provides

Coordinate with Health Care Cost Transparency Board through use of CN board/public entity

Other State Approaches

		Alabama	Connecticut	Hawaii	Massachusetts	New York	Vermont
1	Develop a Statutory Purpose Specific to CN	✓			✓	✓	✓
2	Creation of a Board/Planning Entity	✓	✓		✓	✓	✓
3	Flexibility and Burden of Proof for Need	✓	✓	✓	✓	✓	✓
4	Add Statutory Provisions to Address Inequities – Additional Requirements	✓			✓	✓	
5	Add Statutory Provisions to Address Inequities – Fee Structure, Other	✓	✓	✓	✓		✓

Next Steps

- Consider feedback and direction from Department of Health
- Eliminate or expand on findings
- Conduct further research on applying potential changes in WA
- Identify options and approaches for implementing new approaches
- Develop report content

Questions and Discussion

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