



Washington State Board of Health

Overview of TAC Review of NBS

Process and Criteria

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WASHINGTON STATE 
BOARD OF HEALTH

Overview

- Technical Advisory Committee Overview
- Options for condition review
- Voting results
- Discussion and next steps



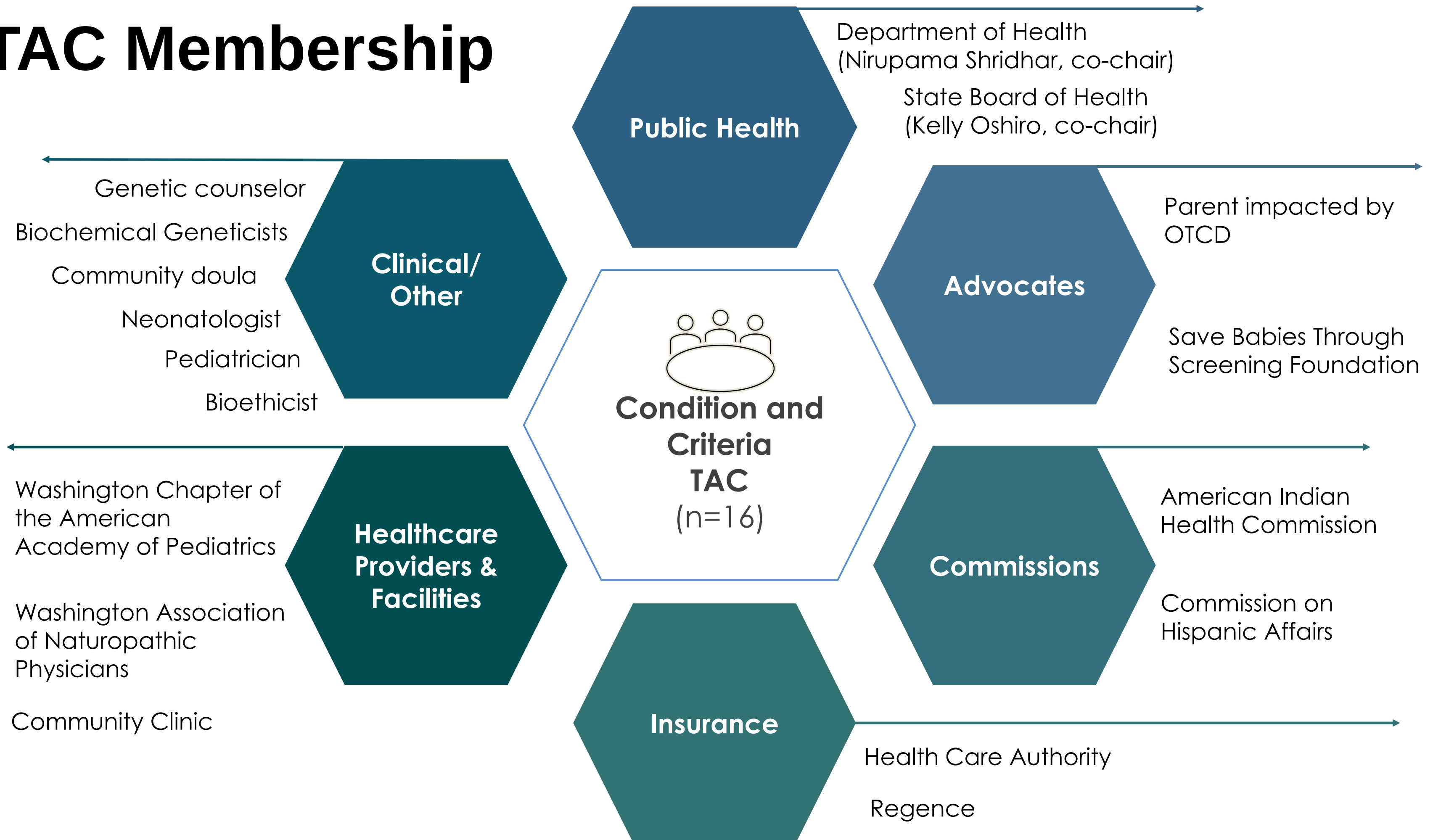
TAC Purpose

TAC convened October 28 to review the Board's current process and criteria for adding conditions to the mandatory newborn screening panel to:

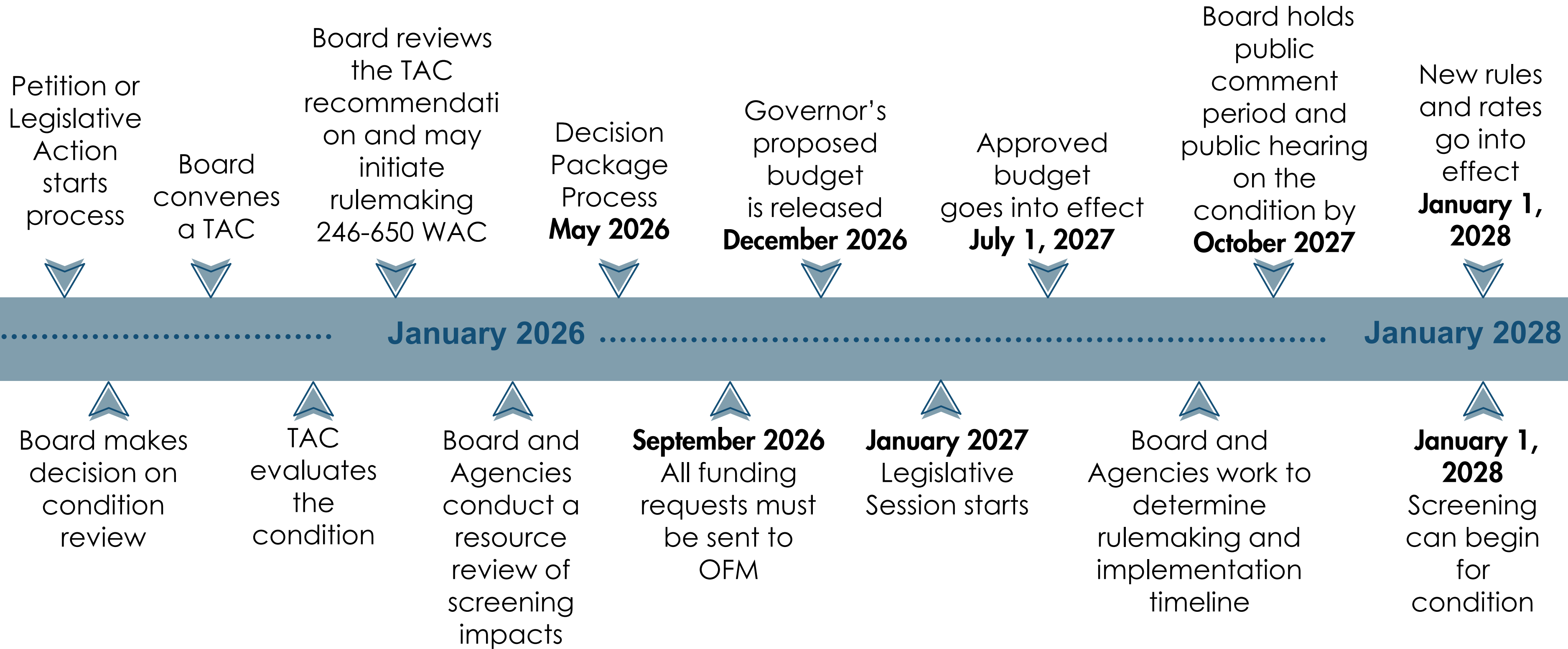
- Address rapid advancements in newborn screening
- Streamline condition review process
- Modernize five criteria and strengthen overall process



TAC Membership



NBS Process Timeline



Timeline Annotations 1-5

1. If a condition review request is made through a petition, the Board has 60 days to review and respond to the petition.
2. Adding a new condition may require the DOH and HCA to request an increase to the newborn screening fee. An increase may cover the cost of the new test(s), staff time, follow-up services for babies with positive screens, and other programmatic and administrative expenses.
3. If there is an FDA-cleared kit for the new test(s), the time to implementation can follow the above schedule. If not, implementation will take longer. The FDA modified LDT oversight in May 2024. The WA PHL can perform LDTs already in effect when the rule change was made. Any modification or new LDT must be approved through the FDA.
4. Agency division concept papers for DP budget requests must be submitted in the spring (May), after the most recent Legislative session, for agency review and consideration. Once the agency has approved the request, formal DP development occurs through the end of July/early August. Agency DP approvals depend on the state budget. If OFM is cautioning agencies that there's a tight budget, getting new DP requests approved can be challenging.
5. Each year, January 1 and July 1, updated MCO rates typically go into effect.

List of Abbreviations/Acronyms

- Decision Package (DP)
- Food and Drug Administration (FDA)
- Laboratory-Developed Test (LDT)
- Managed Care Organization (MCO)
- Office of Financial Management and Budget (OFM)
- Public Health Lab (PHL)
- Technical Advisory Committee (TAC)
- Washington Administrative Code (WAC)
- Washington State Board of Health (Board)
- Washington State Department of Health (DOH)
- Washington State Health Care Authority (HCA)

Options for Condition Review

Option One

Ad Hoc Only

Washington's current process

Conditions nominated for review through petition or legislative direction

Review for evidence to ensure Qualifying Assumption met

Determine if TAC may convene

Option Two

RUSP Alignment + Ad Hoc Committee

Washington newborn screening panel follows federal panel

- Recommended Uniform Screening Panel (RUSP)

Still allow condition nomination through petition or legislative direction

Option Three

RUSP Meets WSBOH Qualifying Assumption + Ad Hoc Committee

Conditions on the RUSP would assume Qualifying Assumption met

- Evidence review not needed by SBOH

All RUSP conditions reviewed by a TAC

Still allow condition nomination through petition or legislative direction

Condition Review Voting Summary

Option	Vote
1. Ad Hoc Only (current process)	0
2. RUSP Alignment + Ad Hoc	4
3. RUSP Meets WSBOH Qualifying Assumption + Ad Hoc	12
4. Unsure or I need more information	0



Condition Review Voting Summary

Do you recommend that the Board put a timeline in place for reviewing RUSP nominated conditions?	Vote
Yes	15*
No	0

If you recommend a timeframe, how long would you like it to be?	Vote
Two-year review process	14
Other	1

*One TAC member abstained from this round of voting.



Criteria Review Discussion

Preliminary discussion of the five criteria

1. Available Screening Technology
 - **Suggestion: provide benchmarks for sensitivity, specificity, false positives, false negatives**
2. Diagnostic Testing and Treatment Available
 - **Suggestion: define “available treatment”**
3. Prevention Potential and Medical Rationale
4. Public Health Rationale
 - **Suggestion: consider available resources for all of Washington, especially rural communities. Also focus on outreach and education.**
5. Cost-benefit/Cost-effectiveness

TAC suggests continuing criteria review at the next TAC meeting

Board Member Discussion

For Board Member discussion

- Does the Board agree with the TAC's recommendation for condition review, the Federal RUSP meets the Qualifying Assumption?
- Does the Board agree with the 2-year timeframe to review RUSP conditions?

If the Board agrees to move forward with the TAC's recommendations, some considerations:

- How to respond to petitions for conditions that are undergoing review by the federal committee?
- How to respond to petitions for conditions that have been previously denied by the federal committee?



Board Member Next Steps

Possible action: The Board may consider the following-

- The Board declines the Newborn Screening TAC's recommendation for the Board to assume that conditions on the Federal RUSP meet the Board's qualifying assumption

OR

- The Board accepts the Newborn Screening TAC's recommendation for the Board to assume that conditions on the Federal RUSP meet the Board's qualifying assumption. The Board directs staff to update WSBOH NBS Process and Criteria document and include 2- year timeframe to review RUSP conditions. TAC continue review of criteria at next TAC meeting.



THANK YOU

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