

Meeting Summary

Consensus Standards Approval Committee – Measure Evaluation Web Meeting

The National Quality Forum (NQF) convened the Consensus Standards Approval Committee (CSAC) for a web meeting on July 28-29, 2020 to evaluate Fall 2019 Track 1 cycle measures.

Welcome, Introductions, and Review of Meeting Objectives

Apryl Clark, NQF Chief of Staff, welcomed the Committee and participants to the web meeting. Thomas Kottke, CSAC Chair, and Melissa Danforth, CSAC Vice-Chair provided welcoming remarks. Shantanu Agrawal, NQF President and CEO also welcomed the committee on behalf of NQF and introduced NQF's new Senior Vice President for Quality Measurement, Sheri Winsper, to the Committee.

Ms. Clark reviewed the meeting objective regarding the evaluation of 29 Fall 2019 Track 1 measures and reminded participants of changes made to the Fall 2019 cycle due to COVID-19. In order to provide greater flexibility for stakeholders and continue the important work in quality measurement, NQF extended commenting periods and adjusted measure endorsement timelines for the Fall 2019 cycle. Commenting periods for all measures evaluated in the Fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered one of two tracks. Measures that did not receive public comments or only received comments in support of the Standing Committees' recommendations were assigned to Track 1 and were reviewed during the meeting. Measures that required further action or discussion from a Standing Committee were assigned to Track 2 and deferred to the Spring 2020 cycle. Track 2 measures will be reviewed during the CSAC's meeting in November.

Ms. Clark also reminded everyone that NQF made an exception to the CSAC voting quorum for the meeting. Considering the recent COVID-19 global pandemic, some CSAC members may need to focus their attention on the public health crisis. In order to provide greater flexibility and continue CSAC's important work to endorse measures, NQF made an exception to the CSAC voting quorum policy. For this meeting only, 80% of CSAC members will need to be present to vote. Previously, all (100%) CSAC members were required to be present to vote.

Ms. Clark asked CSAC members to introduce themselves and provide any disclosures of interest relevant to the measures discussed during the meeting. Due to disclosed interests, Lisa Freeman was recused from discussion and voting for Behavioral Health and Substance Use measure NQF 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO). Additionally, Kevin Kavanagh was recused from discussion and voting on Patient Safety measure NQF 3533e: Hospital Harm – Severe Hyperglycemia.

Ms. Clark also reminded CSAC members of the voting procedures. As in previous meetings, the committee had the option to vote on all measures in a particular topic area at once, without voting on each individual measure. For each topic area, the committee first voted if they would like to vote on all measures at once. If at least one person on the committee did want to vote on all measures together, the committee would vote on each measure separately.

Behavioral Health and Substance Use

Samuel Stolpe, NQF Senior Director, summarized the Behavioral Health and Substance Use (BHSU) Fall 2019 Track 1 measure review cycle. The BHSU Standing Committee reviewed and recommended one new measure and two maintenance measures for endorsement:

- 2800 Metabolic Monitoring for Children and Adolescents on Antipsychotics
- 2801 Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics
- 3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Dr. Stolpe noted that during the BHSU Standing Committee's evaluation of NQF 2800 and NQF 2801, the Committee discussed how antipsychotic medication prescribing in children and adolescents has increased rapidly in recent decades. These medications can increase a child's risk for developing serious metabolic health complications associated with poor cardiometabolic outcomes in adulthood. Moreover, antipsychotic medications may be effective treatment for a narrowly defined set of psychiatric disorders in children and adolescents but are often prescribed for nonpsychotic conditions for which psychosocial interventions are considered first-line treatment. The BHSU Standing Committee agreed that these were important measures given the increased prescribing.

Related to NQF 3541, the BHSU Standing Committee noted that nearly 60% of opioid abuse fatalities originate from opioids prescribed within practice guidelines, which suggests the need for more information in the care and management of individuals on long-term opioid therapy to reduce occurrences of opioid-related adverse drug events.

Dr. Stolpe further outlined the BHSU Standing Committee's concerns that some of the measures were not demonstrating year-over-year improvement. The BHSU Standing Committee discussed if this lack of movement was because the measures do not have continued opportunity for improvement, the measures are addressing an especially challenging area of healthcare, or if the measures were not sufficiently incentivized through accountability applications.

CSAC Discussion

The CSAC discussion was centered on broader issues impacting NQF measures that do not exhibit overall year-over-year improvement. The CSAC noted the BHSU Standing Committee's concerns relative to NQF 2800 and NQF 2801 which lead to a further discussion on topped out measures—quality measures that do not have significant opportunity for improved performance. CSAC members expressed concern with continuing to endorse measures that have high levels of performance. This could lead to increasing measurement burden with limited improvements in quality. CSAC members also discussed that there is not a standardized definition or set of thresholds associated with topped out measures and whether that should be considered in the future. A representative from the Centers for Medicare and Medicaid Services (CMS) clarified that there are reasons that CMS may keep measures that are known to be topped out within federal quality and performance programs, including that such measures may be needed to ensure that accountability entities maintain focus on quality issues associated with the topped out measures. CSAC members encouraged NQF to continue the discussion on topped out measures and how to address them throughout the measure portfolio.

The CSAC noted that the three measures had strong support by the BHSU Standing Committee and no comments from the public or NQF membership in opposition to their endorsement. The CSAC unanimously endorsed the three measures.

Cancer

Nicole Williams, NQF Director, summarized the Cancer Fall 2019 Track 1 measure review cycle. The Cancer Standing Committee reviewed and recommended six maintenance measures for endorsement:

- **0219** Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer
- **0220** Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB Stage III hormone receptor positive breast cancer
- **0383** Oncology: Plan of Care for Pain Medical Oncology and Radiation Oncology (paired with 0384)
- **1858** Trastuzumab administered to patients with AJCC stage I (T1c) III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy
- **1859** KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
- **1860** Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

Ms. Williams and Karen Fields, Cancer Committee Co-Chair, provided summaries of the Cancer Standing Committee's evaluation meeting discussions. Ms. Williams and Dr. Fields noted that during the Cancer Standing Committee's evaluation of NQF 0219 and NQF 0220, the Committee discussed that progress in performance had been made but a performance gap and disparities persist. This warranted continued measurement. Regarding NQF 0383, patient representatives on the Cancer Standing Committee stressed the importance of this measure and of providing better patient education about medications prescribed to them. The Cancer Standing Committee did not have any concerns with NQF 1858, 1859, or 1860.

CSAC Discussion

The CSAC expressed no concerns with the Cancer Standing Committee's recommendations and unanimously endorsed all six recommended measures.

Cardiovascular

Amy Moyer, NQF Director, summarized the Cardiovascular Fall 2019 Track 1 measure review cycle. The Cardiovascular Standing Committee reviewed one new measure and five maintenance measures. Three measures were recommended for endorsement:

- **0071** Persistence of Beta-Blocker Treatment After a Heart Attack
- 0965 Discharge Medications (ACE ARB and beta blockers) in Eligible ICD CRT-D Implant Patients
- **3534** 30-Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (TAVR)

Three measures were not recommended for endorsement:

- **0670** Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low Risk Surgery Patients
- **0671** Cardiac stress imaging not meeting appropriate use criteria: Routine testing after percutaneous coronary intervention (PCI)
- **0672** Cardiac stress imaging not meeting appropriate use criteria: Testing in asymptomatic, low risk patients

Ms. Moyer provided summaries of the Cardiovascular Standing Committee's evaluation meeting discussions. Ms. Moyer noted that during the Cardiovascular Standing Committee discussion of NQF 0071 the Committee discussed the evolution of the definition and treatment of myocardial infarction and the definition of medication persistence versus medication adherence. Regarding NQF 0965, the Cardiovascular Standing Committee discussed new and specialized medications for heart failure and determined the measure appropriately accounts for these advances. The Cardiovascular Standing Committee's discussion of NQF 3534 focused mainly on missing data and the resulting impact on measure risk adjustment and exclusions. For NQF 0071, 0965 and 3534, the Cardiovascular Standing Committee did not have any concerns and recommended them for endorsement.

Ms. Moyer noted that during the Cardiovascular Standing Committee's discussion of NQF 0670, 0671, and 0672, the Committee observed a disconnect between the focus of the NQF measure evaluation criteria and appropriate use measures. For these measures, the underlying literature contained multiple expert opinion statements, with limited empirical data. The Cardiovascular Standing Committee followed the NQF Guidance for Evaluating Evidence for Measures of Appropriate Use and used exceptions to accept the expert opinions as sufficient evidence. For all three measures, the Cardiovascular Standing Committee noted that the developer did not provide updated performance gap data since the original 2011 submission and that this previous data did not correspond to the measure as specified. The Cardiovascular Standing Committee determined the information provided was insufficient to evaluate the current performance gap.

CSAC Discussion

The CSAC had no concerns with the measures recommended for endorsement and unanimously endorsed them. The CSAC inquired if there are other appropriate use measures in the NQF Cardiovascular portfolio or if there will be gap left by the three measures not recommended for endorsement. Ms. Moyer noted that there is an additional appropriate use measure for cardiac imaging that remains endorsed. The CSAC voted to remove endorsement from the measures that were not recommended by the Cardiovascular Standing Committee. Nine members voted to remove endorsement and one voted to return the measures to the Cardiovascular Standing Committee for reconsideration.

Geriatrics and Palliative Care

Kathryn Goodwin, NQF Director, summarized the Geriatrics and Palliative Care Fall 2019 Track 1 measure review cycle. The Geriatrics and Palliative Care Standing Committee reviewed and recommended one maintenance measure for endorsement:

• 1623 Bereaved Family Survey

Ms. Goodwin and Geriatrics and Palliative Care Committee co-chair Deborah Waldrop gave a brief overview of the measure as well as an overview of two overarching issues that arose during the Geriatrics and Palliative Care Standing Committee's evaluation of this measure. The overarching issues included concerns raised by the Scientific Methods Panel (SMP) and the application of NQF's use criterion. Because the SMP rated this measure low on validity, the Geriatrics and Palliative Care Standing Committee started their validity discussion with a deliberation of the SMP's rating, the rationale for that rating, and a vote on whether the Geriatrics and Palliative Care Standing Committee chose to accept that rating. Concerns raised by the SMP included that the risk adjustment model did not include sociodemographic status (SDS), particularly race/ethnicity, and that the beta-binomial values presented as part of the construct validity were too low. The developer shared that they had updated testing results demonstrating stronger beta-binomial values and strong odds ratios and that they were able to share formally during the post-meeting public comment period. Regarding the measure's risk adjustment model, the developer clarified that this measure is developed for use by the U.S. Department of Veterans Affairs (VA) and that the VA's strong preference is to not apply risk adjustment to measures. There was concern about obscuring the source of variation in measure performance. Per NQF process, the SMP may recommend discussion points to the Standing Committee regarding the use of SDS in risk adjustment models but may not fail a measure solely for this reason. The Geriatrics and Palliative Care Standing Committee felt this was sufficient rationale to overturn the SMP rating and passed the measure on the validity subcriterion.

In terms of use, the developer has been working to put a plan in place for public reporting, but as a maintenance measure, NQF requires that it be publicly reported within six years of initial endorsement. The Geriatrics and Palliative Care Standing Committee accepted the developer's plan for public reporting but strongly stressed that the measure should be publicly reported. The Geriatrics and Palliative Care Standing Committee stated they expect to see the measure reported when it returns for its next maintenance endorsement.

CSAC Discussion

During their discussion, the CSAC raised concerns about how the validity and use criteria were applied. CSAC members were not comfortable with the measure meeting the validity subcriterion due to the wide variation presented in the beta-binomials. The CSAC also raised concerns that the Geriatrics and Palliative Care Standing Committee chose to overturn the SMP's rating on validity; however, the developer noted that the data evaluated by the SMP was not current. Updated data are now available that were not presented to the SMP. Regarding use, the CSAC raised concerns that the measure is only reported in VA sites and if endorsed, would be available for other populations that have not been previously evaluated for this measure. The developer responded that public reporting of this measure is dependent on VA leadership approval, but they are pursuing reporting for private facilities and nursing homes. A CMS representative also indicated that there has been collaboration among several federal agencies, and this measure may be more readily accessible in the future on public reporting websites. The CSAC voted to overturn the Geriatrics and Palliative Care Standing Committee's recommendation for continued endorsement and returned NQF 1623 to the Standing Committee for reconsideration.

Neurology

Matthew Pickering, NQF Senior Director, summarized the Neurology Fall 2019 Track 1 measure review cycle. The Neurology Standing Committee reviewed and recommended two maintenance measures for endorsement:

- **0661** Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation within 45 minutes of ED Arrival
- **1952** *Time to Intravenous Thrombolytic Therapy*

Dr. Pickering and the Neurology Standing Committee Co-chairs, David Knowlton and Dr. David Tirschwell, presented a brief overview of the measure as well the overarching issues that arose during the Neurology Standing Committee's review. Dr. Pickering mentioned that both measures are noncomplex, process measures and therefore, they were not reviewed by the Scientific Methods Panel. The Neurology Standing Committee did not raise any major concerns regarding NQF 1952 or NQF 0661 and unanimously recommended both measures for continued endorsement.

With respect to the overarching issues, Dr. Pickering mentioned the Neurology Standing Committee commented on the importance of timely stroke care and treatment, as documented by clinical practice

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guidelines. During the Neurology Standing Committee deliberations, some Committee members commented that the procedural time windows seemed arbitrary and not completely suitable for certain clinical operations, specifically within the emergency department. The Neurology Standing Committee suggested to the developer that they review the related clinical performance of these time windows and modify the respective time frames as needed to ensure updated, accurate, and appropriate time frames in the future.

Dr. Tirschwell added that the treatment for acute ischemic stroke has evolved significantly since the inception of these measures. He stated that there has been a shift from these times frames in ways that NQF 0661 and those alike, do not quite capture. Despite these concerns, Dr. Tirschwell stated that the Neurology Standing Committee recognized that these measures are still an important measure of quality, even if the parameters of the measure and those alike should change to meet the current standards of care. A CSAC member inquired if there are any other measures that consider newer time frames. Dr. Tirschwell stated that there have not been new stroke performance measures that have come before the Neurology Standing Committee since the substantial shift in the standard of care for acute ischemic stroke, but there are other organizations that are currently working on measures for submission.

CSAC Discussion

The CSAC had minimal discussion, noting that the two measures were straightforward, received unanimous voting from the Neurology Standing Committee, and there were no major concerns. The CSAC unanimously voted to uphold the Neurology Committee's recommendation for continued endorsement.

Patient Experience and Function

Samuel Stolpe, NQF Senior Director, summarized the Patient Experience and Function Fall 2019 Track 1 measure review cycle. The Patient and Experience and Function Standing Committee reviewed and recommended one maintenance measure for endorsement:

• 0425 Functional Status Change for Patients with Low Back Impairments

Dr. Stolpe noted that NQF 0425 was reviewed by the Scientific Methods Panel and given high ratings for both reliability and validity. It was further discussed that the measure developer, Focus on Therapeutic Outcomes (FOTO), has several comparable endorsed patient reported outcome performance measures (PRO-PMs) focusing on functional status. Dr. Stolpe further reviewed the Patient Experience and Function Standing Committee's observations that patients with low back impairments with functional status deficits are very common in rehabilitation therapy and may severely impact people of any age. Functional deficits affect large numbers of people leading to substantial morbidity, high resources use, severity of illness, and is a leading cause of poor quality of life. Dr. Stolpe noted that this measure was not regarded as controversial by the Patient and Experience and Function Standing Committee and did not have any public or NQF member comments. This was reinforced by Patient Experience and Function co-chairs, Chris Stille and Gerri Lamb, who reviewed some of the issues that the Patient and Experience and Function Standing Committee resolved during the course of discussion, such as subjectivity of patient response, differences in younger and older patients in functional improvements, and the burden of data collection for PRO-PMs.

CSAC Discussion

The CSAC had limited discussion regarding NQF 0425. The CSAC unanimously voted to uphold the Patient Experience and Function Standing Committee's recommendation for continued endorsement.

Patient Safety

Matthew Pickering, NQF Senior Director, summarized the Patient Safety Fall 2019 Track 1 measure review cycle. The Patient Safety Standing Committee reviewed and recommended one new measure and three maintenance measures for endorsement:

- 0684 Percent of Residents with a Urinary Tract Infection (UTI) (Long Stay)
- **0686** Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long Stay)
- **2456** *Medication Reconciliation: Number of Unintentional Medication Discrepancies per Medication Per Patient*
- 3533e Hospital Harm Severe Hyperglycemia

Dr. Pickering presented a brief overview of the measures as well as an overarching issue that arose during the Patient Safety Standing Committee's evaluation. When discussing NQF 2456, the Patient Safety Standing Committee identified an overarching issue with the definition of public reporting. In particular, the concern was around a measure being used in a public reporting program, but the actual results of the measure (i.e. measure rate) are not reported to the public. The Patient Safety Standing Committee also emphasized the importance of appropriate risk-adjustment, particularly when discussing NQF 0684 and 0686. Considering the underlying risk of an outcome in populations may differ, is it vital to account for that variation in performance measurement. Patient factors such as comorbid conditions can increase the risk of a condition (e.g. a UTI) as well as the community prevalence of the disease. The Patient Safety Standing Committee did not have any concerns with NQF 3533e.

CSAC Discussion

A CSAC member commented that they were in support of previous discussions around public reporting for medication reconciliation and hopes the measure developer will find them useful due to importance of public reporting. Another CSAC member commented that they were surprised to see that NQF 3533e was not specific to the type of diabetes. However, the CSAC member stated that this was not a major issue of concern. The CSAC voted on each measure individually due to an identified recusal and voted unanimously to endorse each measure.

Prevention and Population Health

Nicole Williams, NQF Director, summarized the Prevention and Population Health Fall 2019 Track 1 measure review cycle. The Prevention and Population Health Standing Committee reviewed and recommended one new measure and one maintenance measure for endorsement:

- 0658 Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- 3484 Prenatal Immunization Status

Ms. Williams provided a brief overview of the measures and overarching issues that arose during the Prevention and Population Health Standing Committee's evaluation. As brought up for other topic areas, the Prevention and Population Health Standing Committee raised concerns of topped out measures, specifically NQF 0658 which has a mean performance score of 100%. The Prevention and Population Health Standing Committee raised that a high reliability score could be the result of selection bias for CMS reporters, and the minimum case count of 10 may be insufficient for reliability testing. Another

concern raised by the Prevention and Population Health Standing Committee is the need for data on racial, ethnic, and socioeconomic status disparities in performance testing.

CSAC Discussion

One CSAC member discussed the need for race and ethnicity data from CMS in order to adequately evaluate the measures. A representative from CMS stated that the agency had limited statutory authority to collect data which made obtaining the data challenging. In addition, the data is often not standardized which limits the ability to compare the data across programs and settings. CMS continues to identify opportunities to address this issue. One CSAC member asked a question regarding NQF 0658 to clarify if it included only colonoscopies or also genetic screenings and other new technology, to which NQF responded that the measure is specific to colonoscopies and does not indicate if it would be applicable to identifying genetic markers. The measure developer stated that the measure is primarily an overuse measure to prevent overuse of colonoscopies within identified patient population. Prevention and Population Health Committee Co-Chair Thomas McInerny confirmed the committee understood the measure as an overuse measure when voting.

The CSAC voted on the two measures separately. NQF 0658 was endorsed with nine votes in favor of the recommendation and two votes to return the measure to the Prevention and Population Health Standing Committee for reconsideration. The CSAC voted unanimously to endorse NQF 3484.

Primary Care and Chronic Illness

Samuel Stolpe, NQF Senior Director, summarized the Primary Care and Chronic Illness (PCCI) Fall 2019 Track 1 measure review cycle. The PCCI Standing Committee reviewed and recommended three maintenance measures for endorsement:

- 0577 Use of Spirometry Testing in the Assessment and Diagnosis of COPD
- 1800 Asthma Medication Ratio
- 2856 Pharmacotherapy Management of COPD Exacerbation

Dr. Stolpe outlined the PCCI Standing Committee's primary reasons for recommending NQF 0577, 1800 and 2856 for continued endorsement. Spirometry testing is recommended by the Global Initiative for Chronic Obstructive Lung Disease as the preferred method for diagnosing COPD. Despite being the gold standard for diagnosis and assessment of COPD, spirometry testing is underused. Earlier diagnosis using spirometry testing supports a treatment plan that may protect against worsening symptoms and decrease the number of exacerbations. The prevalence and cost of asthma have increased over the past decade, demonstrating the need for better care management. Appropriate medication management for patients with asthma could reduce the need for rescue medication—as well as the costs associated with Emergency Room visits, inpatient admissions and missed days of work or school.

When discussing NQF 0577, the PCCI Standing Committee noted a continuing opportunity for improvement in the performance gap of the measure and an existing barrier of getting patients to follow up at a provider's office. The performance gap of the measure was questioned as it relates to data supporting clinical disparities and the issue of using race as a marker within diagnoses. Additionally, the PCCI Standing Committee stressed the importance of having disparities data available based on patient self-identification of race and ethnicity, rather than by the provider. A similar concern regarding race and ethnicity data from health plans surfaced during the discussion of NQF 1800. The developer shared that health plans do not provide race and ethnicity data although providers may have that information, it does not accompany claims data.

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Dr. Stolpe shared the PCCI Standing Committee's analysis that US guidelines currently supporting asthma management do not reflect recommendations from European guidelines on the use of longacting beta agonist and corticosteroid combination inhaler therapies for acute exacerbations as well. The PCCI Standing Committee expressed that the developer should monitor these evidence-based best practices for potential measure updates. This was further reinforced by supportive comments from the Committee co-chairs, Dale Bratzler and Adam Thompson.

CSAC Discussion

The CSAC noted that the measures were recommended by the PCCI Standing Committee by relatively wide margins and did not have many controversial issues associated with them. The CSAC unanimously voted to uphold the recommendation for continued endorsement for the three measures.

Surgery

Amy Moyer, NQF Director, summarized the Surgery Fall 2019 Track 1 measure review cycle. The Standing Committee reviewed and recommended one maintenance measure for endorsement:

• 0696 STS CABG Composite Score

Ms. Moyer explained that this measure is a composite consisting of four domains comprised of 11 individual NQF endorsed cardiac surgery measures. The Surgery Standing Committee agreed that the data on disparities were compelling across the individual domains, with increased risk for morbidity and mortality demonstrated for the female sex and African American race. The Surgery Standing Committee and developers discussed the challenges of converting measure scores to star ratings. The Surgery Standing Committee noted that the size of the confidence intervals could influence the star rating assigned. The developer acknowledged this and added that there is no perfect method for assigning star ratings but that they are using well-accepted and tested methodology.

CSAC Discussion

The CSAC had no concerns regarding this measure or the Surgery Standing Committee's recommendation and unanimously endorsed the measure.

Public Comment

During a public comment opportunity, an individual asked about NQF's definition of a topped out measure. NQF informed participants that there is no definition or threshold for a topped out measure, but may be a consideration in the future.

Next Steps

There were 25 measures from the Fall 2019 cycle that were endorsed during this meeting. These measures will undergo a 30-day appeals period from August 3, 2020 at 9:00 am ET to September 1, 2020 at 6:00 pm ET. Any party may request an appeal of an NQF endorsed measure during this time. For an appeal to be considered, it must include information that clearly demonstrates there was a procedural error that is reasonably likely to affect the outcome of the original endorsement decision, or there is new information or evidence that was unavailable at the time the CSAC made its endorsement decision that is reasonably likely to affect the outcome of that decision.