Business Case Form and Instructions

***INSTRUCTIONS****: This form is primarily for measure developers and its use is voluntary. The form includes instructions for making a business case meeting the triple aim of improved health, improved care, and reduced cost. Using it can help measure developers fulfill the deliverable requirement of submitting an adequate business case for a new measure or an existing measure being reevaluated during maintenance. Use this form in conjunction with the* [*Business Case Development*](https://mmshub.cms.gov/measure-lifecycle/measure-conceptualization/business-case/overview) *section on the CMS MMS Hub.

Please note: All CMS measure contract deliverables must meet accessibility standards as mandated in Section 508 of the Rehabilitation Act of 1973. This template is 508 compliant. You may not change the template format or non-italicized text. Any change could negatively impact 508 compliance and result in delays in the CMS review process. For guidance about 508 compliance, CMS’s* [*Creating Accessible Products*](https://www.cms.gov/es/node/1549751) *website* *may be a helpful resource.****NOTE TO NON-CMS-CONTRACTED MEASURE DEVELOPERS****: You may edit the Project Overview language to reflect your organization does not have a measure development contract.

Measure developers should submit an INITIAL draft Business Case during the measure conceptualization process and present an UPDATED Business Case before measure implementation begins. Although there may be limitations to some of the data and details initially, the expectation is the measure developer will provide more detailed information in updated submissions.*

*In some cases, a measure developer may be able to use text from their CMS consensus-based entity (CBE) submission to complete this form and vice versa, a practice CMS encourages.****COST CONSIDERATION IN MEASURE DEVELOPMENT:*** *Financial impact of the measure should be only part of the consideration when making a business case and it may not be the most important consideration. We provide more detailed information for addressing costs here to support users who may have less experience with cost models. Users may find this information helpful when completing sections:* ***Measure Impact on Health Care Costs****;* ***Resources Required for Measure Implementation****; and* ***Costs of Clinical Care****.

Cost Analysis (CA) is a form of economic valuation in which measure developers assign dollar values to activities and outcomes. For most measures, the business case is concerned with two types of costs: 1) costs to payors (e.g., Medicare, Medicaid, other payors) as a result of a measure’s (intended or unintended) impact; and 2) costs to clinicians and measured entities associated with implementing a measure. Using a CA approach, measure developers can translate costs into savings when calculating potential impacts because the measure developer may regard any action taken to cause future spending to fall below the level of current spending as a cost saving. Not addressed here are two other approaches for economic valuation used to determine the effectiveness of a program/activity, Cost Effectiveness Analysis (CEA) and Cost-Benefit Analysis (CBA).****Costs to Payors***

*In measure development, the outcome of interest (“outcome”) is typically a health outcome or health care process defined by the measure logic model. These outcomes refer to the specific changes in measured entities’ or patients’ behavior, knowledge, skills, status, or level of functioning. The measure’s “impact” refers to the fundamental intended or unintended changes occurring in organizations, communities, or systems as a result of measure implementation.

Although it is desirable to quantify the final outcomes in dollar values, it is not always an easy task to assign a dollar value to an outcome. In these cases, the measure developer can state an outcome as an interim measure without assigning a dollar value (e.g., percentage of smokers who quit smoking for 6 months due to an implementation of a cessation program). The measure developer should state the ultimate cost as an impact by assigning a dollar value to the corresponding change (e.g., potential reduction in health care costs attributed to smoking-related diseases). Measure developers should report costs to payors in the* ***Measure Impact on Health Care Costs*** *and* ***Costs of Clinical Care*** *sections.****Costs to Health Care Measured Entities Implementing Measures*** *Cost considerations for measure implementation can stem from direct/tangible costs (e.g., a dollar amount to upgrade software, develop a tool, or hire new staff), from indirect/intangible costs (e.g., overhead or administrative expenses), or costs difficult to quantify (e.g., changes to clinical workflow expenses), if any. These are the costs associated with collecting and reporting measure data, as well as investments in quality improvement initiatives related to the measure. Measure developers can assign costs to various resources (e.g., staff hours devoted to that activity, proportion of office space used) and summed to calculate a total cost of implementation. In this business case template, the measure developer should consider these costs separately from costs to payors and should not include in the impact on health care costs analysis. Rather, measure developers should include these costs in the* ***Resources Required for Measure Implementation*** *section.****PLEASE DELETE THIS INTRODUCTORY SECTION (TEXT ABOVE THE LINE) AND REPLACE THE FORM-RELATED REFERENCES SHOWN ON THE LAST PAGE OF THE FORM WITH YOUR OWN REFERENCES BEFORE SUBMISSION. CMS REQUIRES NO SPECIFIC FORMAT FOR REFERENCES BUT BE COMPLETE AND CONSISTENT.

CMS-CONTRACTED MEASURE DEVELOPERS MUST USE THE MOST CURRENT PUBLISHED VERSION OF ALL TEMPLATES*** ***AND SHOULD CHECK THE*** [***CMS*** ***MMS HUB***](https://mmshub.cms.gov/) ***FOR UPDATES BEFORE SUBMISSION.***

**Project Title: *List the formal project title as it should appear on official documentation.*Date:**Information included is current as of *insert date (MM/DD/YYYY)*.

**Project Overview:**The Centers for Medicare & Medicaid Services (CMS) contracted with *measure developer name* to develop *measure (set) name or description*. The *contract* name is *insert name*. The *contract* number is *project number*.

**Measure Description:***Use the Measure Title as listed in the Measure Information Form (MIF). It should be brief and include the measure focus and the target population. Measure developers may use text from their CMS CBE submission, if available.***Numerator Statement:***Provide all information required to identify the cases (e.g., the target process, condition, event, or outcome) from the target/initial population, such as definitions, specific data collection items/responses, and code/value sets. Measure developers may use text from their CMS CBE submission, if available.***Denominator Statement:***Provide a brief narrative description of the target/initial population proposed for measurement. Measure developers may use text from their CBE submission, if available.*

**Net Benefit:***Summarize the key findings from the business case analysis that most effectively provide the rationale and strengthen the justification for the measure, balancing benefits against increased provider, implementer, or patient burden, or implementation and clinical costs. Examples of these benefits may include*

* *lives saved*
* *functional status improvements*
* *patient experience and perception improvements*
* *reduced complications, readmissions*
* *cost savings to the payor (e.g., Medicare), patients, measured entities, or other interested parties.*

*The measure developer may also include benefits associated with improved measure feasibility, such as reduced reporting burden, minimal implementation costs, or improved measure validity/reliability.*

**Measure Alignment with** [**Meaningful Measures**](https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20) (select all that apply):*Check all the Meaningful Measures strategic goals applicable to this measure:*[ ] person-centered care
[ ] equity
[ ] safety
[ ] affordability and efficiency
[ ] chronic conditions

[ ]  wellness and prevention

[ ]  seamless care coordination
[ ] behavioral health

**Measure Uses (select all that apply):***Check all the current and planned uses for the measure:*[ ] public reporting
[ ] public health/disease surveillance
[ ] payment program
[ ] regulatory and accreditation programs payment and network selection
[ ] professional certification or recognition
[ ] quality improvement with benchmarking (external benchmarking to multiple organizations)
[ ] quality improvement (internal to the specific organization)

Precise Statement of Need, Current Performance, including any disparities:

*Justify why this measure is necessary. Describe the measurement or performance gap the measure will address.*

*The purpose of this section is to determine the current baseline of the measure or measure focus and demonstrate whether there are gaps in performance. Report mortality and morbidity statistics relating to the process or outcome under consideration, if appropriate. The information provided in this section should reflect the best available data and analytic approaches based on the measure’s current state of development or use. For instance, measure developers should provide performance data for a measure currently in use, while findings from peer-reviewed literature may be the most appropriate evidence base for a new measure. Include a brief justification for the approach selected for demonstrating current performance and disparities. Use the references obtained through information gathering.

Measure developers may use text from their CMS CBE submission, if available.

Examples of acceptable approaches for demonstrating current performance and disparities include*

* *findings from peer reviewed literature*
* *performance data from related measures, e.g., measures in related domains in different health care settings, or from previous versions of the measure*
* *performance data from the measure in use as specified*
* *for survey-based measures, initial performance data collected during survey development and testing*
* *results from beta testing of a related measure*
* *empirical analysis, which may include techniques such as regression modeling.*

*If disparities exist, describe the current performance by subpopulations. Consider potential disparities based on these factors (to the extent possible), but include other factors as appropriate:*

* *facility size and other characteristics*
* *age group*
* *race/ethnicity*
* *sex*
* *insurance status, including Medicaid and dual-eligible*
* *income status*
* *education*
* *overall health, mental health*
* *social determinants/drivers of health, such as housing and food security.*

**Measure Impact on Care and Health Outcomes:***Describe the linkages and steps between the measure focus and anticipated improvements to care and health outcomes. Include details and supporting evidence for the processes that lead to improvements in the* [*intermediate*](#IntermediateOutcome) *and/or health outcome(s).

Estimate the expected performance of the measure as it relates to the quality of care and health outcomes. If you expect improvement in certain subpopulations, use stratified estimates. Quantify the size of improvement that is reasonable to expect based on literature, performance of similar measures, or initial evidence of the measure’s performance or impact based on measure testing. Provide a time frame and trajectory for anticipated improvements. For instance, does the measure developer expect the measure to impact care or outcomes within one year of implementation or within five years? Some measures will focus on care processes with a near real time effect on the outcome (e.g., a measure of emergency transport time intended to improve trauma survival) while other measures may have an expected lag in the time needed to impact the outcome (e.g., management of HbA1c in patients with diabetes to prevent negative outcomes). During measure maintenance, compare actual performance to the estimates and report the differences along with analysis and recommendations.

Measure developers may use text from their CMS CBE submission, if available.

Examples of acceptable/desirable methods for impact assessment include*

* *Create a logic model showing the relationship between measure antecedents, measure, and desired outcomes, with supporting references.*
* *Review clinical guidelines to support the logic model, if appropriate.*
* *Review the incidence and prevalence, sizes of affected populations of patients, and measured entities.*
* *Utilize findings from peer-reviewed literature reviewed in the* ***Current Performance*** *section to establish assumptions about expected improvements, including for subgroups.*
* *Utilize expert assessments and feedback from clinical staff, patients, and other stakeholder groups to support the logic model or impact assumptions.*
* *Utilize empirical modeling to estimate the expected performance of the measure.*

*Consider utilizing a table to summarize expected health impacts.* [*Table A*](#Table_A) *is an example table shell; however, there are many acceptable formats. Such a table might show the expected number of additional patients who would receive care given an assumed level of improvement (e.g., for a process measure) and the hypothesized downstream benefits (e.g., reduced utilization). You may use this table to list alternative scenarios or assumptions expected to change the measure impact, as with a sensitivity analysis. Please provide complete citations.**Table A. Estimated benefits due to (measure name)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Scenario*** | ***Current Measure Performance*** | ***Relevant Population*** | ***Estimated Performance Improvement*** | ***[Change in Care Delivered]*** | ***[Net Change in Desired Outcome]*** |
| *[E.g., X% expected change]* | *X%* | *XX.X million* | *X%* | *X.X million additional treatments received* | *X.X million avoided ED visits* |
| *Etc.* |  |  |  |  |  |
| *Etc.* |  |  |  |  |  |

*Please add reference(s) for estimates.

Describe assumptions, variables, and formulas used to construct the analysis of resources required for measure impact on care and health outcomes.***Measure Impact on Health Care Costs (if any):***Estimate the expected performance of the measure as it relates to health care costs. Health care costs refers to the cost to payors (e.g., Medicare, Medicaid, private payors), and to the extent possible, measured entities and patients. Follow the approach detailed in the* ***Measure Impact on Care and Health Outcomes*** *section. If there is no anticipated impact on health care costs state “none” and include a brief explanation of why there is still a strong business case for the measure (e.g., lives saved, improved health outcomes).

Describe acceptable/desirable methods for impact assessment under* ***Measure Impact on Care and Health Outcomes****. In addition, consider use of appropriate economic models when calculating savings, e.g., return on investment analysis.

If applicable, consider utilizing a table to summarize expected health care cost impacts.* [*Table B*](#Table_B) *is an example table shell; however, there are many acceptable formats. Such a table might show the expected saved costs to Medicare for target/initial population or subpopulations given an assumed level of improvement, net of cost increases associated with care improvements (e.g., as for a process measure). You may use this table to list alternative scenarios or assumptions expected to change the measure impact, as with a sensitivity analysis. Please provide complete citations.*

*Table B. Estimated cost impacts due to (measure name)*

|  |  |  |  |
| --- | --- | --- | --- |
| ***Scenario (see*** [***Table A***](#Table_A)***)*** | ***[Cost of Additional Care]*** | ***[Cost of Avoided Care]*** | ***[Net Change in Cost/Savings]*** |
| *[E.g., X% expected change]* | *$X.X million*  | *$X.X million* | *$X.X million* |
| *Etc.* |  |  |  |
| *Etc.* |  |  |  |

*Please add reference(s) for cost estimates.

Describe assumptions, variables, and formulas used to construct the analysis of measure impact on health care costs.*

**Influencing Factors:***Describe factors that may influence adoption, implementation, and performance. Factors may include*

* *legislation and regulation*
* *CBE endorsement*
* *competitive market pressures*
* *data infrastructure*
* *stakeholder perception and buy-in*
* *technical assistance*
* *reimbursement policy*
* *reporting burden and other concerns related to feasibility*
* *concerns related to data quality or methodological issues that may affect scores.*

*Provide data to document any observed factors affecting measure implementation and/or performance. If there are any concerns about the feasibility of implementing a measure or for the measured entities responding to the measure, explicitly state those concerns in this section.

NOTE: If resources required may be an influencing factor, list them here but provide data and analysis as indicated in the section* ***Resources Required for Measure Implementation****.***Resources Required for Measure Implementation:***There may be costs to the measure implementer (measured entity) to capture and report measure data, including the use of staff time, software, health information technology, electronic health record (EHR) or intero*perability needs, data purchase, licensing fees for codes or instruments, required audits, costs associated with [*Information Collection Review*](https://www.reginfo.gov/public/do/PRAMain)*, as required by the Paperwork Reduction Act. Estimate, calculate, and report these costs in the business case. Describe and quantify the resources necessary to implement the measure, including staff time and other direct and indirect costs. The measure developer may present estimated costs per provider or across all impacted measured entities; it may be appropriate to consider scaling of costs for large vs. small measured entities.

Measure developers may use text from their CMS CBE submission, if available.*

*Describe assumptions, variables, and formulas used to construct the analysis of resources required for measure implementation.

NOTE: Resources required for measure implementation are different from the costs of providing additional clinical care. Address* ***Costs of Clinical Care*** *in the next section.***Costs of Clinical Care:***There may be a cost of clinical care required to improve performance. Cost of clinical care refers to the cost to payors (e.g., Medicare, Medicaid, private payors) and to the extent possible, measured entities of the care patients receive. For process measures of underuse, include the additional cost of receiving the recommended care in the discussion. This may also apply to outcome measures if there is a need for additional care to improve outcomes. Estimate, calculate, and report these and other related costs in the business case. Describe and quantify the resources necessary to implement the desired changes in care, including staff time and other direct and indirect costs.

Examples of acceptable/desirable components or approaches include*

* *Build on analyses and literature review presented in* ***Measure Impact*** *sections to develop estimates of costs of clinical care, including costs associated with improved performance.*
* *If you present data associated with the costs of clinical care in the* ***Measure Impact on Health Care Costs*** *section, you may refer to that section.*
* *If applicable, explore common alternative clinical interventions when calculating costs for outcome measures.*

*Describe assumptions, variables, and formulas used to construct the analysis of costs of clinical care.

NOTE: The costs of clinical care are different from the investments needed to implement the measure. Report implementation costs under the* ***Resources Required for Measure Implementation*** *section.

NOTE: The measure developer should incorporate the costs of clinical care into the* ***Measure Impact on Health Care Costs*** *section as costs of additional care.***Potential Unintended Consequences of the Measure (if any):***Document, initially and during maintenance, the incidence of untoward effects of the measure as reported in the literature or gathered from other sources, such as empirical analyses. Report the costs of treating potential unintended complications.

Measure developers may adapt text from their CMS CBE submission, if available.

Examples of potential unintended consequences include*

* *reduced access to care/stinting care*
* *pressure on measured entities to avoid hospitalizations*
* *avoidance of sicker patients by measured entities (i.e., “cherry picking”)*
* *unfair comparisons between measured entities or rewarding lower costs without balancing quality performance*
* *shift in coding and billing practice patterns*
* *shift in clinical practice patterns needed to implement the measure*
* *additional barriers to care, including inadequate access to specialists or lack of coverage for alternative therapies proposed by the measure*
* *pernicious incentives for patients, e.g., patients seeking opioids may seek out measured entities with low performance scores related to prescribing alternative therapies*
* *potential for mortality measures to affect such things as palliative care decisions.*

*Describe assumptions, variables, and formulas used to construct the analysis of potential unintended consequences. If desired, the measure developer may describe potential mitigation strategies.***Limitations of Analysis:***Describe limitations in the data or assumptions used in the business case, especially the sections:* ***Current Performance; Measure Impact on Care and Health Outcomes; Measure Impact on Health Care Costs; Costs of Clinical Care****. Measure developers should complete this section since all measure development efforts encounter limitations.

NOTE: The intent of this section is not to cite the limitations associated with the measure itself.

Measure developers may use text from their CMS CBE submission, if available.*

*[Please delete these references and add your own references in this section before submission]*

# References

Centers for Medicare & Medicaid Services. (n.d.). *Creating accessible products*. Retrieved September 28, 2023, from https://www.cms.gov/es/node/1549751

Centers for Medicare & Medicaid Services. (n.d.). Meaningful measures 2.0: Moving to measure prioritization and modernization. Retrieved September 28, 2023, from <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20>

Partnership for Quality Measurement. (n.d.). *Endorsement and maintenance*. Retrieved September 28, 2023, from <https://p4qm.org/EM>

U.S. General Services Administration and the Office of Management and Budget. (n.d.). Information collection review. Retrieved September 28, 2023, from <https://www.reginfo.gov/public/do/PRAMain>