Advancing Health Care Research and Decision-Making Centered on Patients and People with Disabilities

DRAFT

Drafting Note: Entirety of the below should be placed in section of law governing the state Medicaid Program, including parallel provisions in fee-for-service and managed care, as applicable.

(a) Definitions.

(b) Standards for Patient-Centeredness in Research & Analysis. The [Department]shall ensure that any portfolio of research and analysis relied upon for decision-making, whether provided by a state agency or a third party, impacting enrollee access to healthcare treatments and services, meets standards of patient-centeredness. The [Department] shall publicly provide a summary of patient-centeredness standards for any such analysis that includes, but is not limited to:

1) Evaluation of a range of research and analysis that includes outcomes prioritized by patients and people with disabilities within a specific disease area. If necessary, the [Department] will commission a survey of patients to identify relevant outcomes within a disease area.

2) Evaluation of a range of research and analysis that looks at relevant patient subgroups to ensure consideration of important differences in preferences and clinical characteristics within patient subpopulations.

3) Scientific Rigor: The [Department] shall require research and analysis to comply with good research practices, defined as consideration of the full range of relevant, peer-reviewed evidence (e.g., real-world evidence, research from range of sponsors including manufacturers), avoid patient harm through over-interpretation of findings of "inconclusive" evidence of clinical differences and instead allow time for conduct of additional research.

Drafting Note: Section (c) may be added to the section of law governing the activities of the P&T Committee/DUR Board or other oversight entity responsible for determining the scope of benefits. It may also be drafted to place a burden on Medicaid Managed Care plans to provide such engagement and transparency. Will likely need state-specific drafting.

(c) Engagement of Patients and People with Disabilities & Transparency. Prior to any action that impacts enrollee access to healthcare treatments and services, the [Department] shall provide opportunity for stakeholder engagement and transparency surrounding any research and analysis, whether provided by a state agency or third party, relied upon for decision-making that would impact enrollee access to healthcare treatments and services. At a minimum, the process shall include:

1) Providing stakeholders with a meaningful opportunity to comment* on the retention of any vendor providing research and analysis to the [Department];

2) Publication of a comprehensive list of research and analysis relied upon by the [Department] to allow for meaningful notice and comment process (including a meaningful opportunity for public comment*);

* *Drafting Note – Check state specific notice requirements*

3) Any decision that relies on an advisory panel or expert panel shall require deliberation to occur through public meeting;

4) Presentation of any research and analysis relied upon for decision-making in public meetings or publicly released prior to deliberation, while protecting the confidentiality of information that is legally protected from public disclosure;

5) The requirement of full disclosure into funding sources and conflicts of interest of any third party providing research and analysis to the State;

6) The prohibition of sole source contracts for research and analysis to ensure reliance on a range of evidence;

7) Preparation of an annual report assessing enrollee access to healthcare treatments and services. The report should assess the impact of any form of utilization management on access to care with a specific analysis of the impact on persons with disabilities and chronic illness. The report shall be submitted to the state legislature, be posted on the state Medicaid website by [xxxxx date], and the agency shall provide an opportunity for public comment.

(d) Prohibition on Reliance on Discriminatory Measures. The [Department] shall not develop or utilize, directly or indirectly through a contracted entity or other third-party, a dollars-per-quality adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.

(e) Appeals and Physician Override Mechanisms. The [Department] may not implement any policy limiting patient access to healthcare treatment and services which does not contain an appeals or physician override mechanism. Physicians may not be discriminated against or otherwise negatively impacted for utilizing available physician override mechanisms.

** Drafting Note – Check state specific notice requirements*