

BAKER v. CAMPBELL
Agreement of Experts
January 21, 2004

DEFINITIONS:

- ***Serious medical need***
“Serious medical need” is defined as a valid health condition that, without timely medical intervention, will cause (1) unnecessary pain, or (2) measurable deterioration in function (including organ function), or (3) death, or (4) substantial risk to the public health.

- ***Formulary***
The “formulary” is defined as a list of medications approved for use by practitioners. It is developed and monitored by a Pharmacy and Therapeutics committee, with physician representation from the ADOC’s medical care provider’s Alabama operation. The formulary process may require step-therapy to assure cost-effectiveness. The formulary process may require pre-authorization for selected therapeutics because of their safety profile, injudicious use by non-specialists or high cost. There is a clear and efficient mechanism for practitioners to request a waiver for non-formulary medications, based on medical necessity. The formulary and waiver process for requests for waivers of the formulary are an integral part of the medical necessity decision-making process. Non-formulary requests will be considered similarly to requests for off-site care.

- ***Medical Necessity***
The following principles are intended to assist in making medical necessity decisions that are soundly-based and consistent:
 - **The intervention must be intended to be used for a medical condition.**
A health intervention is an activity undertaken for the primary purpose of diagnosing, preventing, improving or stabilizing a disease, illness or injury. Activities that are primarily cosmetic, custodial, or part of normal existence (*e.g.*, baldness or impotence), or undertaken primarily for the convenience of the patient, family, or practitioner are not considered serious medical needs.

 - **The published evidence should demonstrate that the intervention can be expected to produce its intended effects on health outcomes.**
The published evidence used to justify a determination must be peer-reviewed, reporting scientifically well-controlled studies. The evidence should directly relate the intervention to improvements in health.

 - **There is no other intervention that produces comparable or superior results in a more cost-effective manner.**

- **The intervention's expected beneficial effects on health outcomes should outweigh its expected harmful effects.**
- **Nothing in these principles should prohibit the ADOC or PHS, at their discretion, from covering health interventions that do not meet these criteria.**
- **Medical necessity will be determined by the RMD in conjunction with the site responsible physician.**
- *Clinical Guidelines*

The ADOC's medical care provider will submit quarterly reports to the ADOC and to the ADOC's monitor, as well as to the consultant of this agreement. These reports will include counts of visits by specialty or diagnostic test, lag time to appointments by specialty, and turnaround time on reports to primary physicians. Data will be tracked and trended with a twelve-month tail.

The ADOC's medical care provider will also report quarterly on hospital discharges by diagnosis and length of stay. Data will be tracked and trended with a twelve-month tail and reported to the Department's consultant.

The care recommendations of the specialist will be acknowledged in the medical record and considered. Any deviation from or override of the specialist's recommendations must be affirmatively medically justified in the medical record.

Prostheses, including dental, and devices such as hearing aids, will be repaired

Exhibit A

isolation for converters with positive symptoms, and surveillance activities to determine whether there is intramural transmission of tuberculosis.

- Comprehensive medication management program to minimize lag time from prescription to first dose, to maintain continuity of medication, to eliminate gaps in prescription renewal, and to counsel and document legitimate refusals of medication. The prescribing practitioner should be notified of any patient who is not taking prescribed medication, as measured by missing doses on three consecutive days.
- Dental care shall focus on the timely treatment of emergencies, the restoration of restorable teeth in lieu of extraction, and on dental hygiene. Cleaning will be based on the following protocol: diabetics, seizure patients, HIV-positive inmates, cardiac patients, and inmates at risk for periodontal disease shall receive a cleaning on an annual basis. All other inmates shall have the opportunity for a cleaning at least once every 24 months.
- Clinical staff shall all undergo a rigorous credentialing process that includes primary verification of licensure and restrictions or sanctions, and inquiry with the National Practitioner Data Bank.
- Licensed staff shall not practice beyond the scope of their license.
- Consulting physicians shall be qualified in their specialty, as defined by their hospital privileges. Nurses must have graduated from an accredited RN or LPN program and hold applicable licenses. All other ancillary personnel must meet applicable state regulatory requirements and training standards. Personnel working under a license or certification who are subject to restrictions or conditions imposed by the licensing agency, or who have formal complaints filed against them, must immediately report such restrictions, conditions, or complaints to the Medical Director.
- Medical and nursing staff must be currently certified in cardio pulmonary resuscitation (“CPR”), according to the certification schedule defined by the Red Cross or American Heart Association. All health care staff who sees patients shall receive regular training to maintain competence in current methods for diagnosing and treating medical complications associated with acute and chronic illness, including the ability to recognize when referral to a physician or specialist is necessary.
- Implementation of a comprehensive quality management program with a program description and annual work plan. Activities will include communicable disease control, pharmacy and therapeutics, mortality review, clinical guidelines, and adherence to standards. In addition there is regular performance measurement on access to on-site and off-site care, availability of specialty care, continuity (during incarceration and on release), coordination between health care practitioners, complaints, medication management, acute care, chronic disease care and communicable disease.

- Focus studies should be performed where problems exist. Barriers should be identified and interventions should be designed to reduce the barriers. Re-measurement should occur to document meaningful improvement.
- Data on performance measurements should be tracked and trended.
- Data shall be discussed at a quality management committee, with appropriate analysis and plans documented in the minutes.
- Mortality reviews shall be timely and self-critical.
- An annual program summary and evaluation shall be published within three months of the end the year, documenting an inventory of activities, trended performance data, self-critical analysis, and plans for the upcoming year based on findings of the past year.
- Medically required special diets will be ordered when determined to be necessary by the responsible physician.

POLICIES AND PROCEDURES TO BE DEVELOPED/REFINED BY ADOC:

The following policies and procedures are subject to approval by the contract consultant, approval that will not be unreasonably withheld:

- Nurse screening protocols
- Clinical Guidelines for chronic disease and communicable disease, including viral hepatitis
- Quality management plan, work plan, template for evaluation, performance measurement procedures, and mortality review
- Medication management
- Staff training
- Bloodborne pathogen control plan
- Airborne pathogen control plan
- MRSA control plan including surveillance, diagnosis, treatment, hygiene, environmental sanitation, and exchange and laundering of linens and clothing

Exhibit A

STAFFING:

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Exhibit A

Feasibility: The measure should be amenable to collection, computation, and implementation in a way that complements existing health system approaches to performance measurement. The measure should be:

- Clearly specified
- Inexpensive to produce
- Adhere to accepted conventions of confidentiality
- Available in a timely manner
- Amenable to audit
- Resistant to gaming

Frequency of Measurement

Each measure is to be performed every three months, unless otherwise indicated. When performance on any individual measure equals or exceeds 90% in two successive quarters, that individual measure can be performed every six months. When performance falls below 90% on any individual measure, the measurement periods defaults to every three months.

Performance measures marked with asterisks necessitate clinical judgment during the audit. Appropriate disciplines are noted on the tool.

Nursing Sick Call

1. Seen within 36 hours of request, or 72 hours on weekends
2. Assessment appropriate to chief complaint*
3. Relevant vital signs charted*
4. Treatment plan appropriate* (e.g., refer to higher level practitioner on third visit for same symptoms)

Urgent Care

1. Care timely*
2. Appropriate vital signs documented*
3. Appropriate MD/PA/NP assessment and plan*

Clinical Guidelines – annual review

1. The clinical guidelines and related disease management program will be based on nationally-accepted guidelines for asthma, diabetes, HIV, epilepsy, hyperlipidemia, viral hepatitis and hypertension, as defined above
2. For communicable disease, the guidelines conform to CDC, ACET, ACIP, BOP etc. for STDs, TB, prevention of viral hepatitis and HIV, MRSA, etc.

Chronic Disease—PPD Positive

1. Clinical evaluation and treatment decision within 14 days*

Exhibit A

Chronic Disease—Viral Hepatitis

1. All screening, diagnostic procedures, and treatment will occur consistent with the medical care provider's clinical guideline as referenced in ¶ 11 of the Settlement Agreement.

Chronic Disease—Asthma—(Applies only to Moderate and Severe Asthma)

1. Peak flow on intake or within past 3 months
2. On inhaled steroid, as medically necessary, if the patient is classified as moderate persistent or worse for more than four weeks.
3. Followed chronic disease guideline; assessment includes degree of control; strategy to improve outcome if control is fair or poor or status worsened*

Chronic Disease—Diabetes [to comport with Diabetes Settlement Agreement]

1. Blood sugar on intake
2. Hemoglobin A1C performed quarterly (unless stable <7.0, then every 6 months)
3. Level ≤ 7.0 or documented clinical strategy within 45 days of intake (or arrival at facility) or within past 3 months. Patients with high levels may have interim objectives of levels greater than 7.0.
4. Dilated retinal exam within the past 12 months
5. Lipid evaluation within the past 12 months
6. Foot exam within the past 3 months
- 7.

Exhibit A

3. Followed chronic disease guideline; assessment includes degree of control; strategy to improve outcome if control is fair or poor or status worsened *

Exhibit A

Credentialing – Every 12 months

1. Assess 100% of MD/PA/NP files with validation of current license and DEA certificate
2. Assess 100% of nursing files with validation of current license
3. Assess 100% of dental files with validation of current license
- 4.