

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 and its medical care provider will develop and implement chronic disease guidelines that are reasonably-based on the most current nationally-accepted guidelines for the management of chronic and communicable disease, customized for corrections. The targeted conditions will be prevalent among inmates. They will be conditions for which there is a sound scientific basis that interventions make a difference in morbidity and mortality. Further, these will be conditions targeted as national priorities by the Surgeon General (Healthy People 2010) or the National Committee for Quality Assurance (HEDIS Quality Compass). These guidelines are published and periodically updated by:

Diabetes	American Diabetes Association
Hypertension	NIH-JNC
Asthma	NIH – NAEP
HIV	U.S. DHHS
MRSA	Bureau of Prisons and/or CDC
Tuberculosis, STDs	CDC NCHSTP
Viral hepatitis	U.S. DHHS

Performance expectations (*e.g.*, monitoring timelines) and performance measurements will be summarized and made available to practitioners. The clinical guidelines will be reviewed and updated annually, as necessary.

**ELEMENTS OF ADEQUATE CARE AND TREATMENT
FOR INMATES WITH SERIOUS MEDICAL NEEDS:**

- Access to care is not unreasonably impeded.
- Access to effective and appropriate diagnostic testing, consultation, medication and therapeutic interventions.
- Adoption of nationally accepted clinical guidelines for chronic and communicable disease. This includes at least quarterly monitoring, with a physician visit and appropriate diagnostic evaluation, for primary prevention and early detection of complications of illness. Patients shall be evaluated for their degree of control, and plans should be documented to improve control, when necessary. For patients in good control, with conditions such as hypertension or epilepsy, who

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have been stable for more than six months, visits may be scheduled every six months so long as medication continuity is maintained.

- Continuity of care including continuity of medication on transfer, at St. Clair, and on release.
- Health assessment for any incoming inmate who has not had such an evaluation, or whose documentation is not available, within the past year.
- Use of a continuously updated formulary. Requirements for step-therapy are acceptable when medically legitimate.
- Timely access to formulary and non-formulary medication. The non-formulary process should not pose any barriers to time-urgent care.
- Timely access to outside specialty care when medically necessary. The utilization management process should not pose any barriers to time-urgent care. No prospective approval is required in these circumstances.

All specialty referrals are to be made by a physician. The only exceptions to this policy for an individual mid-level practitioner can be made by the regional medical director, in writing. Nurses involved in the utilization management process may approve referrals for specialty care or may ask for additional demographic or clinical information. Only physicians may issue denials or recommendations for alternative medical care. Alternative recommendations or denials will only be made in consideration of the individual patient's condition. When an alternative recommendation or denial is issued, the rationale will be clearly specified.

The medical director, or delegate, must give prior approval for all outside referrals not anticipated by guidelines. The medical director should consider medical information on the individual patient. The referring physician should have the opportunity for informal and formal review of any alternative recommendation.

The approval process should not exceed five business days for non-urgent care, measured from the date that requested information is supplied. The consideration process shall not be unreasonably delayed.

As part of the database, the ADOC's medical care provider will track all requests for outside care by date, specialty or test, and medical reason. The tracking should include the disposition of the utilization management decision. This list will form the basis for external review.

As part of the database, the ADOC's medical care provider will also track the date of the appointment, and whether the patient was seen. This information will form the basis for studying the time lag to outside care.

All non-urgent referrals will be accomplished within 60 days, or sooner according to medical necessity. The patient will be seen by the referring physician every thirty days until such time as the referral has been accomplished. The purpose of these visits is to assess whether there is any reason to intervene in the process.

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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 and/or replaced in a timely manner, consistent with the medical condition of the patient. Turnaround time should not exceed 90 days, unless there are sound medical reasons.

- Access to medically trained personnel for emergency transportation to hospitals.
- Medical information is transmitted as medically appropriate to outside medical caregivers. Medical records are available to ADOC consultant, Plaintiffs' counsel, and any other authorized monitor/consultant. Medical records are timely transferred when the inmate moves from one facility to another.
- Co-payments do not apply for care required by clinical guidelines or care requested by physicians, such as follow-up care. Co-payments shall be waived for control of serious communicable disease control, *e.g.*, access to care for boils and tuberculosis.
- Inmates will not be charged co-payments for being informed of the results of laboratory or diagnostic tests.
- Sick call shall not be conducted between 11:00 PM and 6:00 AM. Any inmate presenting to the nurse more than two consecutive times for the same symptoms, with deterioration or no improvement, will be referred to a higher-level practitioner. Sick call will be available to inmates from every area of the facility at least five days per week. Nurses performing sick call will be trained in the use of nurse screening protocols, with emphasis on the timing of appropriate referral to a higher-level practitioner. Nurses will be trained in physical assessment to implement these protocols. The assessment and treatment plan will be appropriate to the complaint, including timely referral to a higher-level practitioner, if necessary.
- Annual screening for tuberculosis will include a review of symptoms, PPD for non-positives, chest x-ray within 96 hours for TB skin test converters, respiratory

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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.

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- 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

STAFFING:

- Designated medical authority (MD) for facility
- Clear chain of command for quality oversight and utilization management
- One FTE physician equates to 40 hours of on-site, hands-on, medical care
- This facility must have at least 40 hours physician care on-site, and 40 hours of a mid-level practitioner such as a nurse practitioner.
- This facility must have sixteen hours of RN coverage in every 24-hour period; LPN's must be supervised.
- Sufficient staff to perform performance measurement and other quality management functions
- For each additional 200 inmates over the census that existed on January 21, 2004, staffing shall be increased as follows: 0.2 FTE physician or 0.3 FTE mid-level practitioner.

PERFORMANCE MEASUREMENT:

Criteria for Performance Measurement¹

Relevance: the measure should address features of the system or practitioner that are relevant to the stakeholder likely to make judgments about quality of care, and that are likely to motivate efforts toward improvement in quality. The measures should

- Represent priority clinical and financial issues
- Identify areas of care with measurable opportunities for improvement
- Represent activities for which a facility or practitioner is directly accountable and might be modifiable
- Define a scale with magnitude and direction that is unambiguous in its relation to quality
- Motivate improvements in quality, efficiency and cost-effectiveness

Validity: Validity of a measure is influenced by measurement errors and biases, which if unresolved, make the reliability and interpretation of the measure questionable. To be valid, a measure should:

- Have a high level of consensus regarding its meaning and importance
- Produce comparable results when measured by different auditors (reliability)
- Produce comparable results when measured in different settings, different time periods, or with different data sources
- Measure directly the process or outcome it is intended to measure
- Be able to be adjusted for other population characteristics which might affect the measure but which are not necessarily under the control of the facility

¹ Criteria adapted from "Criteria for Measure Selection, National Committee for Quality Assurance

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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*

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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. Urine microalbumin within the past 12 months unless one prior positive has been documented then it is no longer needed to test.
8. Blood pressure controlled or documented attempt (threshold 130/80)
9. Low-dose enteric coated aspirin prescribed
10. Followed chronic disease guideline; assessment includes degree of control; strategy to improve outcome if control is fair or poor or status worsened *

Chronic Disease—HIV

1. CD4 count and viral load within 45 days of intake or arrival at facility, or within past 3 months
2. PCP prophylaxis offered within 2 weeks if CD4+ count ≤ 200
3. HAART therapy consideration with documentation in the medical record, within 2 weeks if CD4+ count ≤ 350 or the viral load is $>55,000$ (RT-PCR assay) or $>30,000$ (bDNA assay)
4. Followed chronic disease guideline; assessment includes degree of control; strategy to improve outcome if control is fair or poor or status worsened *
5. Pneumovax once
6. Influenza vaccine annually, October - February

Chronic Disease—Hypertension

1. Blood pressure reading noted at intake
2. Intake blood pressure > 140 systolic or > 90 diastolic: treatment or plan will be initiated within 14 days of identification. The diagnosis of hypertension cannot be made with a single blood pressure reading.

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

Specialty Care Access (Cardiology, Dermatology, Eye, Gynecology, Neurology, Ophthalmology, Orthopedics, Podiatry, Pulmonary, etc.)

1. Progress note reflects need for consultation
2. Consultation ordered by a physician, physician assistant or nurse practitioner
3. Consultation accomplished within 60 days of order
4. Primary care visits every 30 days until visit is accomplished
5. Documentation of follow-up as medically appropriate.

X-Ray (chest)

1. Timely reporting of results, clinician acknowledgment and appropriate follow-up of abnormal chest x-rays within 72 hours after x-ray is performed*

X-Ray (non-chest)

1. Timely reporting of results, clinician acknowledgment and appropriate follow-up of abnormal x-ray within 96 hours after x-ray is performed*

Laboratory

1. Report back within 72 hours as appropriate
2. Clinical acknowledgment and appropriate clinical response*

Medication Administration Records

1. % of blank spaces in the five medication administration books
2. Assess % of refusals (3 consecutive days) in medication administration books
3. Assess % of refusals (3 consecutive days) with appropriate follow-up

Lag Time from Prescription to Delivery of First Dose of Medication

1. Median number of days from prescription to delivery of first dose
2. Examination of cases in longest tenth percentile for barriers

Dental Care

1. Emergency evaluations seen by a licensed, independent health care practitioner within 24 hours
2. "Priority" patients seen within seven days, timely treatment including restoration when appropriate
3. Ratio of restorations to extractions for the trailing three months
4. Dental hygiene visit, including cleaning, within 24 months for inmates in custody for > 24 months
5. Documentation of providing oral health information to patients seen
6. Clear and complete documentation of visits and procedures including medical history

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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. Assess 100% of mental health files with validation of current license

Complaints and grievances (requires a system to track and trend complaints and grievances from inmates through all conduits)

1. Analyze trends in terms of numbers and category distribution
2. Assess % appropriately addressed within 14 days
3. Assess % answered responsive to specific complaint

Utilization Management and Alternative Treatment Plans

1. Timely
2. Medical information considered
3. Requesting practitioner informed with specified reason for the denial or alternative treatment plan
4. Specific alternative treatment plans proposed, where applicable

Pending Off-site Referrals

1. % waiting more than 30, 60, and 90 days
2. 30 day review by primary physician, where applicable

Comprehensive quality management program

1. Quality Management Program Description and Annual work plan
2. Activities include communicable disease control, pharmacy and therapeutics, mortality review, clinical guidelines, and adherence to standards. In addition there is regular performance measurement on access, availability, continuity, coordination, complaints, 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.
3. Focused studies on all identified opportunities for improvement
4. Tracked and trended data on performance measurements
5. Minutes
6. Mortality reviews timely and self-critical
7. Annual program summary and evaluation