



IMPORTANT STATE HEALTH LAW REGULATORY CHANGES - 2010 TO THE PRESENT

Balch & Bingham LLP attorneys focus on State law regulatory issues and have relationships with state regulators at the State Departments of Health, at State Attorneys General offices, at Secretary of State offices and at Medical Licensure, Nursing and Pharmacy Boards. Firm clients receive monthly CON Bulletins and other state regulatory updates. The following is a summary of key State regulatory changes in Alabama, Georgia and Mississippi during Calendar Year 2010 and the first four months of Calendar Year 2011.

ALABAMA

ALABAMA DEPARTMENT OF PUBLIC HEALTH – DIRECTOR OF THE BUREAU OF HEALTH PROVIDER MEDICAL STANDARDS

Rick Harris recently announced his retirement from his position as director of the Bureau of Health Provider Medical Standards, a position held since 1998. Dr. W.T. Geary, Jr. served as the interim director until the appointment of Patricia Ivie, former deputy general counsel to the Alabama Department of Public Health (ADPH), as the new director of the Bureau of Health Provider Medical Standards. ADPH is responsible for licensing health care facilities in Alabama.

ALABAMA STATE HEALTH PLAN

New State Health Plan and Proposed Amendments

On March 15, 2011, the State Health Coordinating Council (SHCC) approved a new State Health Plan (SHP) and the following amendments to the new SHP:

Section 410-2-3.10 - Hospice Services and Section 410-2-4.15 - Inpatient Hospice

The proposed amendments establish January 2013 as the date for the SHCC to present any findings of projected need after a three-year period of collecting and analyzing data for in-home hospices.

Additionally, the amendments require the need methodology for inpatient hospices to be based on average daily census as annually reported to the Alabama State Health Planning and Development Agency (SHPDA), Alabama's CON agency, and allow applicants to provide, as supplemental evidence to support a CON application, data reported annually to the State of Alabama (other than SHPDA) or the federal government.

Section 410-2-4.09 - Swing Beds

The proposed amendment limits rural hospitals to no more than 10 swing beds and allows critical access hospitals to have up to 25 swing beds.

Section 410-2-4-.04 - Additional Planning Policies

The proposed amendment requires all CON-authorized Specialty Care Assisted Living Facilities (SCALF) beds to be included in consideration of occupancy rate and bed need; allows a county's bed need to be increased by 16 SCALF beds if occupancy for the county is greater than 92% based on census data in the most recent full year SCALF annual report published by or filed with SHPDA; allows a facility's bed need to be increased by 16 beds if occupancy for the facility is greater than 92% based on census data in the most recent full year SCALF annual report published by or filed with SHPDA; and requires applications for new freestanding SCALF facilities to request at least 16 beds.

Governor Bentley's Failure to Sign the New State Health Plan

After SHCC's approval, the new SHP and the proposed amendments were sent to Governor Bentley for his signature. Governor Bentley did not sign the new SHP and the proposed amendments. Therefore, the SHP and its amendments have expired. Governor Bentley has indicated his intent to "overhaul" the SHP to lower health care costs and promote free market competition, but no new plan has been revealed.



ALABAMA CERTIFICATE OF NEED REVIEW BOARD

Proposed Rule Changes

On May 18, 2011, the Alabama Certificate of Need Review Board (CON Board) approved for publication two proposed rule changes to the Alabama CON Program Rules and Regulations:

Section 410-1-7-.06 - Filing of a Certificate of Need Application

The proposed amendment requires that only CON applications for substance abuse treatment facilities or psychiatric beds provide proof of publication of notice of application in a newspaper of general circulation. The proposed amendment also abolishes the requirement that such notice be published within 30 days of filing the application.

Section 410-1-8-.02 - Contested Case Before Administrative Law Judge and Section 410-1-8-.05 - Majority Decision

The proposed amendments impose time limitations for contested case hearings before an Administrative Law Judge (ALJ). Specifically, the amendment requires that, unless extended by written agreement by all parties, any public hearing before an ALJ must begin within 45 days of assignment, must be completed within 90 days, and the ALJ must render findings of fact and conclusions of law within 30 days of completion of the transcript.

MORATORIUM ON CON AND SHPD MATTERS AND APPOINTMENT OF NEW CON BOARD MEMBERS AND SHCC MEMBERS

On January 18, 2011, Alabama's newly-elected Governor, Robert Bentley, M.D., issued Executive Order Number 3 placing a moratorium on all CON matters being handled by SHPDA and on all SHPD matters handled by the SHCC. On February 9, 2011, Governor Bentley lifted the moratorium.

Governor Bentley also appointed members to the CON Board and the SHCC. Members of the CON Board are: Dr. Swaid N. Swaid, Dr. Herb Stone, Dr. Bob Sheppard, Neal Morrison, Guice Slawson Jr., General Ed Crowell, Hodges Washington, Dr. Michael Gosney, and Dr. Chris Harmon.

Members of the SHCC are: Dr. Ruth Yates, Dr. James Walburn, Dr. Vera Soong, Ruth Harrell, Dr. Gillis Payne, Dr. McCain Ashurst, Dr. Theodis Buggs, Dr. Tommy Bender, Dr. Jeff Underwood III, Robbie Owen, Brenda Culver, William Smith, Rebecca Thrasher, Judy Merritt, John Killian, Brandon Farmer, Mary Holcomb, Rep. Jim McClendon, Sen. Greg Reed, Ross Gunnells, Mary Sue McClurkin, F. Wayne Pate, and Representative April Weaver.

CON REFORM LEGISLATION

Under existing Alabama law, any party to a contested case involving a CON application is required to appeal an adverse decision by the CON Review Board first to (i) the Circuit Court of Montgomery County or (ii)(a) the county in which the applicant is located or (b) the county in which the new institutional health service is to be located before the decision can be appealed to the Alabama Court of Civil Appeals.

A CON reform bill introduced into the Alabama legislature would provide for a direct appeal to the Alabama Circuit Court of Civil Appeals, thereby bypassing the initial review by the circuit court.

The bill would additionally provide for approved fee rates for ALJs in contested cases. The fee rates would be based on a standard hourly rate established by the Executive Director of SHPDA on an annual basis and be apportioned, on a pro rata basis, among all parties to the contested case hearing.

Finally, the bill streamlines the processing of contested cases by requiring any public hearing before an ALJ to begin with 45 days of assignment to the ALJ and to be completed within 90 days of assignment. The ALJ would also be required to issue a recommended order within 45 days of completion of the hearing transcript.



GEORGIA

DEPARTMENT OF BEHAVIORAL HEALTH AND DEVELOPMENTAL DISABILITIES

In Georgia, behavioral healthcare has taken center stage this year, as the State begins implementing mandates contained in its October 19, 2010 settlement with the U.S. Department of Justice (DOJ). The settlement was reached after the DOJ opened an investigation of the care provided in Georgia's psychiatric hospitals in 2007.

Under the terms of the settlement agreement, the State must undertake a variety of measures to move patients out of institutionalized care and into appropriate community-based settings. Some of the settlement agreement mandates include:

- By July 1, 2011, Georgia must cease all admissions to State Hospitals of persons whose primary diagnosis is developmental disability. The State must gradually move patients in State Hospitals to the community.
- The State must create a program to educate judges and law enforcement regarding developmental disabilities, must audit the quality of current community based providers, and must assess quality annually.
- For individuals with substantial and persistent mental illness, the State must establish various community-based services including Crisis Service Centers (CSUs) to provide 24/7 walk-in clinic services for individuals in crisis (e.g., substance abuse) and Crisis Stabilization Programs (CSPs), 16-bed community based residential services located off State Hospitals' campuses. CSPs provide psychiatric stabilization and detoxification services as an alternative to hospitalization.

Complying with the settlement agreement, the Georgia General Assembly enacted House Bill 343, setting up the regulatory scheme for CSU licensure which, prior to the amendment, were not required to be licensed. CSUs will be licensed and governed by the Department of Behavioral Health and Developmental Disabilities (DBHDD). Statutory amendments require the DBHDD to establish minimum standards and requirements for the licensure of CSUs including:

- CSUs must operate within the guidelines of the Emergency Medical Treatment and Labor Act with respect to stabilization and transfer of patients
- CSUs are prohibited from holding themselves out as, or billing as, a hospital; and
- CSUs must give priority to patients lacking private insurance.

The DBHDD has been, and will continue to be, active in promulgating regulations necessary to establish the services required by the DOJ settlement agreement.

COMPOSITE MEDICAL BOARD – PROFESSIONAL HEALTH PROGRAM

Other recent regulatory developments include the development of a Professional Health Program or PHP for impaired physicians. On May 28, 2010, the Governor signed Senate Bill 252 to establish a professional health program providing for monitoring and rehabilitation of impaired healthcare professionals and authorizing the Composite Medical Board to enter into a contract with a professional organization to conduct such program.

The Composite Medical Board has issued notice of intent to amend and adopt rules related to the establishment of the "Professional Health Program" or "PHP." According to the proposed rules, the Professional Health Program is established for the purposes of (1) coordinating the evaluations and/or assessment of health care professionals, (2) to determining whether those professionals can practice with reasonable care and safety and/or (3) monitoring and rehabilitating impaired health care professionals. The rules are expected to be finalized by July 1, 2011.



MEDICAL CONSENT STATUTE

Recently, Georgia's Medical Consent Statute has been expanded, authorizing adult grandchildren to consent for their grandparents who are patients and any adult niece, nephew, aunt or uncle related to the patient in the first degree to consent for the patient. If the patient does not have a health care agent, a legal guardian or any family member authorized to consent, an adult friend of the patient can provide medical or surgical consent. Furthermore, if none of the aforementioned individuals is authorized and willing to provide consent, the amended statute provides for an expedited judicial process to appoint a temporary medical consent guardian for the patient.

DEPARTMENT OF COMMUNITY HEALTH

Calendar year 2010 brought Georgia a new Republican Governor, Nathan Deal, replacing Georgia's former Governor, Sonny Purdue. The new Governor has shaken up management at the Department of Community Health (DCH). David A. Cook has been appointed Commissioner of DCH. Commissioner Cook formerly served as the Executive Director and Chief Executive Officer of the Medical Association of Georgia (MAG). Prior to coming to MAG, Commissioner Cook had a long career in the legal and legislative arena, including serving as Governor Deal's Chief of Staff.

Commissioner Cook will oversee the Division of Healthcare Facility Regulation, Medicaid and the State Health Benefit Plan. Clyde L. Reese III, formerly the Commissioner of DCH, has been appointed Commissioner of the Department of Human Services, which oversees, among other departments, the Division of Family & Children Services and the Division of Aging Services.

In addition to Commissioner Cook's appointment, Mr. Richard Greene has also been appointed as DCH's new General Counsel. Mr. Greene will serve as chief legal advisor to the Department and the Commissioner, as well as to senior leadership charged with developing operational strategies, and implementing state and federal mandates for the agency.

MISSISSIPPI

MISSISSIPPI STATE HEALTH PLAN – FY 2010 and 2011

FY 2010 State Health Plan

Chapter 5 – Acute Care - Certificate of Need: Acute Care Hospital Need Methodology – Section 102.01

The FY 2010 State Health Plan included a dramatic revision allowing counties in an Underdeveloped General Hospital Service Area and with a rapidly growing population to be considered for the addition of an acute care hospital. Previously, formulas existing to determine need in counties both with and without hospitals were drafted in such a way that a county with an existing hospital would not be able to add a second facility. The ability to add a hospital came with restrictions, however. Any new hospital is limited to 100 beds, and must provide an above average amount of indigent care and Medicaid services, must participate in the Trauma Care System and the State and School Employees' Health Insurance Plan and must establish outpatient services in the adjacent county (if the adjacent county does not have an existing hospital).

FY 2011 State Health Plan

Chapter 5 – Acute Care - Certificate of Need Criteria and Standards for Construction, Renovation, Expansion, Capital Improvements, Replacement of Health Care Facilities, and Addition of Hospital Beds

Subsection 102.03(b) - Projects Which Involve the Addition of Beds

The FY 2011 State Health Plan modified the Need Criterion for an acute care hospital adding additional beds. The modification reduces the required occupancy rate from 70% to 60% during the most recent two years, requires use of a formula that includes "observation patient days" and requires, using that formula, that the occupancy rate be at least 70% during the most recent two years. Further, in the Glossary section, the State Health Plan added definitions of "observation bed" and "observation services", defining an "observation bed" as one "occupied by a patient who is admitted to the hospital for a period of 23 hours and 59 minutes or ...[fewer than] 48 hours."



Chapter 5 – Certificate of Need Criteria and Standards for Diagnostic Imaging Services

Subsection 113.02.01 – Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment including Cardiac only PET Scanner.

Prior to the FY2011 State Health Plan, no “need” requirements existed for obtaining a CON to acquire and provide Cardiac only PET scanning. The FY 2010 State Health Plan modified the need criterion for obtaining a CON for a Cardiac only PET scanner by changing the geographic area considered to the General Hospital Service Area vs. the entire state, by exempting such an application from compliance with the equipment to population ratio and by clearly stating that PET and Cardiac only PET will be evaluated separately when considering the number of required clinical procedures to be performed per year.

Chapter 7 – End Stage Renal Disease

Subsections 104.01 and 104.02.01 - Policies for Establishment and Expansion of Existing ESRD Facilities and Satellite ESRD Facilities

The State Department of Health modified the ESRD CON requirements substantially in its FY 2011 State Health Plan. The revised provisions allow an existing ESRD facility to add stations without obtaining CON review if the facility does not add more than four stations or 15% of its current number of certified stations over a period of two years. If the ESRD facility desires to exceed the number of stations added, it must undergo a CON review and have maintained a 65% utilization rate during the previous 12-month period.

Further, without CON review, an existing ESRD facility may now establish or relocate one home dialysis program to any location within a 5-mile radius of the existing facility. Lastly, when an existing ESRD facility’s stations reach a total of 36, the facility may establish a new 10-station facility without CON review if the new facility is less than one mile from the existing facility. If a Satellite Facility is established within a three mile radius or less of the existing facility, the existing facility must prove a 65% minimum utilization rate during the previous 12-month period, justify the project’s need and document that a new facility is more efficient than expanding the existing facility. If the radius to the new facility is between three and 20 miles from the existing facility, the existing facility must additionally prove that it is at least 30 miles distant from another ESRD facility or obtain that facility’s “written support”. New facilities must include at least 10 stations.

The “Need Criterion” for establishing a limited care renal dialysis facility or relocating a portion of an existing ESRD facility’s stations to another facility was revised in the FY 2011 State Health Plan to require that each ESRD facility in the proposed ESRD Facility Services Area must have an 80% utilization rate.

REVISED CON STATUTE – 2011 MISSISSIPPI LEGISLATIVE SESSION

House Bill 826, approved and signed by Governor Barbour and effective July 1, 2011, amended Mississippi Code § 41-7-201 to provide that appeals of CON orders for health care facility construction, expansion or replacement projects must be made directly to the Mississippi Supreme Court. Also amended is Section 41-7-205 allowing CON projects for services other than single diagnostic therapeutic, rehabilitative, preventive or palliative procedures to qualify for expedited Department of Health review.

MISSISSIPPI BOARD OF MEDICAL LICENSURE

Regulation of Community Based Immunization Programs – Chapter 28

Effective May 2011, the Mississippi Board of Medical Licensure (BOML) added guidance for Community-Based Immunization Programs indicating that such services constitute “the practice of medicine”. Such programs will not be considered “the unauthorized practice of medicine”, however, if the immunizations are administered by a licensed nurse and in accordance with federal or state immunization programs or other programs approved in advance by the Board as long as the nurse is under the general supervision of a Mississippi licensed and resident physician who practices at least 20 hours per week and who assumes responsibility for the “safe conduct” of the program.



Regulation of Nurse Practitioners and Their Collaborating Physicians – Chapter 9, Section 400

The Board of Nursing (BON) and the BOML worked jointly to develop a regulatory amendment to the requirement that nurse practitioners (NPs) have collaborating physicians due to NPs' concerns that collaborating physicians may suddenly and unexpectedly become unable to continue their collaborating physician. The existing regulation provided for a 90-day "grace period" (with a 90-day extension available) for NPs when one of three unexpected events occurred: the death, disability or relocation of the physician. At its March 2011 meeting, the BON expressed the concern that the most common scenario impacting a NP relative to his or her collaborating physician is a revocation or restriction of the physician's license. Accordingly, the BOML proposed amending the regulation to include revocation or restriction of the physician's license as another "trigger" for the 90-day grace period for NPs. According to the most recent proposed version of the regulatory amendment, however, the BOML did not include this scenario as one of the events initiating the grace period.

Also, as certain BOML members expressed concern that the regulation regarding collaborating physicians appeared to regulate NPs, the BOML amended the regulation to expressly state that the NPs operating during a grace period would not be engaging in the unauthorized practice of medicine. The genesis of the BOML's authority to promulgate this regulation is the Board's statutory empowerment to define what constitutes the "unauthorized practice of medicine".

Prescription Guidelines – Chapter 25, Section 1000

The BOML amended its prescription guidelines to permit electronic prescriptions for controlled substances (Schedules II, III, IV and V), as long as the practitioner complies with DEA requirements and is using a certified electronic prescribing system for the transmission of controlled substances prescriptions.

MISSISSIPPI BOARD OF NURSING

Regulation of Nurse Practitioners – Chapter IV

The Mississippi Board of Nursing (BON) finalized several changes to its regulations concerning nurse practitioners. The regulations now provide that if a nurse practitioner's national certification lapses, he or she must stop practicing immediately until the certification is renewed. Also, similar to the proposed BOML amendment, the BON regulations now provide for a 90-day grace period (with a 90-day extension available) in the event that a collaborative physician is unable to continue in that role.

MISSISSIPPI BOARD OF PHARMACY

Effective January 31, 2011, the Mississippi Board of Pharmacy (BOP) significantly revised its Mississippi Pharmacy Practice Regulations that have been in effect since 1999. The changes include a number of additional defined terms, including a change to the definition of "valid prescription." Excluded from the definition of "valid prescription" are orders for prescriptions drugs that the pharmacist knows or should have known were issued by a practitioner when a valid practitioner/patient relationship did not exist, such as when a practitioner prescribes medication on an outpatient basis although he or she has not conducted an appropriate examination of the patient.

The amendments to the pharmacy regulations expand the responsibilities of the pharmacist-in-charge for a permitted facility and those of a consultant pharmacist to an institutional facility, as well as the grounds for disciplinary actions by the BOP against pharmacists and permitted facilities. The amended regulations also establish new requirements for institutional facilities regarding their unit dose dispensing systems and return of medications. Additionally, the BOP has now established a prescription monitoring program overseen by an advisory board and has promulgated administrative procedures rules.

With respect to wholesaler and manufacturer permittees, the 2011 regulations now provide that every business that distributes prescription drugs into this state to an affiliated or related company under common ownership and control of a corporate entity must register biennially with the BOP. Previously, the regulations excluded "intracompany sales."

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