**CAP Advocacy Position**

Federal & State Affairs Committee (FSAC), Approved September 16, 2017

**Title:** Laboratory Benefit Management (LBM), Clinical Decision Support (CDS), and Prior Authorization/Prior Notification Programs and Protocols Administered by Health Insurance Payers

**Position Synopsis**

The College of American Pathologists (CAP) supports laws, legislation and regulation, including advocacy with health insurance payers, that appropriately circumscribes the clinical role of laboratory benefit management (LBM) programs, clinical decision support (CDS) protocols, and Prior Authorization/Prior Notification policies when administered by health insurance payers. In particular, the CAP believes that governmental oversight and regulation of these programs is needed: 1) to prevent conflict of interests by entities that administer these programs; and 2) to ensure that these programs do not conflict with, subordinate, or unduly encumber the practice of medicine.

The CAP believes CDS, LBMs, and Prior Authorization/Prior Notification protocols can add value to the health care system when the use of these is circumscribed in law or regulation to be limited to highly esoteric molecular/genomic testing, or for those tests in which national medical standards or guidelines have been promulgated or widely embraced by the medical community, so as to better inform ordering physician medical judgment.

This advocacy position should not be construed to apply to those LBM, CDS or Prior Authorization/Prior Notification protocols deployed and administered by hospitals, medical delivery systems, or Accountable Care Organizations (ACOs), as these do not engender the policy concerns that are manifest when such program and protocols are administered by health insurance payers, or their affiliates, designees or contractors.
Position

The College of American Pathologists (CAP) supports public policy that regulates laboratory benefit management programs when administered by health insurance payers or their affiliates, designees or contractors. For purposes of this position "Laboratory benefits management program" means a health insurance payer protocol, or program, administered by a health insurance payor, or by another entity under contract with the payer, that dictates or limits health care provider decision-making relating to the use of clinical laboratory/pathology services. The CAP believes that state regulation of LBMs is fundamentally needed to prevent conflict of interests by entities that administer these programs and to ensure that these programs do not conflict with, subordinate, or unduly encumber the practice of medicine. The CAP will also advocate with health insurance payers to effectuate the goals of this position.

With respect to highly esoteric molecular/genomic testing or for tests in which national medical consensus standards or guidelines have been promulgated or widely embraced by the medical community, physician clinical judgment on appropriate test ordering may be enhanced or facilitated by these programs. However, for well-established clinical laboratory/pathology testing that does not fall into the category of esoteric/molecular testing, the CAP believes such programs, when administered by health insurance payers or their affiliates, designees or contractors, pose an unnecessary and counterproductive procedural encumbrance upon the practice of medicine with the potential to improperly curb medically necessary testing in order to benefit the financial interest of the payer. Specifically, CAP advocates that LBM systems under regulations or conditions of operation should:

- be prohibited from exercising control over laboratory/pathology services provided by multiple in-network laboratories to a health insurance payer for their enrollees when the LBM is administered by entity affiliated with a single clinical laboratory;
- only encompass laboratory/pathology services that are esoteric molecular/genomic testing or for tests in which recognized, national medical consensus standards/guidelines are promulgated;
- be prohibited from facilitating business conduct by a health insurance payer that would have an adverse claims impact on the laboratory/pathology service provider who receives an order for services from a health care provider in accordance with law;
• not require a secondary pathologist review of an initial pathologist interpretation and/or diagnostic finding;

• not require or otherwise impel referrals to a designated clinical laboratory when other in-network laboratories are available to perform such services on a timely basis.

In general, CAP advocates that regulations or conditions applicable to CDS, LBM and Prior Authorization/Prior Notification should include that such programs or protocols be:

• transparently based upon peer reviewed, published evidence in medical literature;

• subject to routine and timely updating based upon accepted standards of medical practice and the most current medical knowledge;

• amenable to a physician’s immediate over-ride in the ordering of pathology/laboratory services based upon the medical judgment of the physician regarding the patient;

• prohibited from facilitating business conduct by a health insurance payer that would have an adverse claims impact upon a pathology/laboratory provider who receives an order for services from a health care provider in accordance with law.

With respect to Prior Authorization/Prior Notification programs administered by health insurance plans, the CAP believes that such programs should be limited to only esoteric molecular/genomic testing that could be a significant cost to the health care system. In general, the CAP is concerned that Prior Authorization/Prior Notification protocols administered by health insurance programs, or their affiliates, designees or contractors, impinge on the practice of medicine and could improperly encumber and curtail medically necessary clinical laboratory and pathology services by serving the financial interest of the payer. The CAP believes Prior Authorization/Prior Notification programs administered by health insurance payers should:

• categorically exempt hospitals and surgical centers, in which institutional level protocols should be preeminent and unencumbered or conflicted by health insurance payer protocols;

• for any request be subject to decision by the health insurance payer within 24 hours, and allow for a maximum of ten (10) calendar days for the payer to make any decision on an appeal of an adverse determination, both of which conform to standard advocated and supported by the American Medical Association (AMA).
Furthermore, CAP strongly believes that with respect to LBM, CDS or Prior Authorization/Prior Notification programs or protocols that constitute utilization review by a health insurance payer, it is imperative clinical decisions undertaken by these programs or protocols be administered by providers who are at least as qualified as the prescribing/ordering physician whose decision-making is otherwise subject to utilization review, as is called for under policies espoused by the AMA. In addition, CAP regards any such utilization review activities of physician judgment applicable to patient care undertaken by health insurance payers, or other entities under contract with payers, to be tantamount to the practice of medicine and subject to corporate practice of medicine laws in states where applicable.

**Originating Body**  
Federal & State Affairs Committee