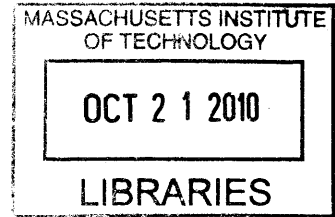


An Analysis of the Differences Between National and Local Coverage Determinations of Medical Procedures in the US

by

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Submitted to the Harvard-MIT Division of Health Sciences and Technology
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Abstract

Medicare coverage policies of medical procedures can be promulgated at a national level by the Centers of Medicare and Medicaid Services (CMS) as National Coverage Determinations (NCDs) or at a local level by Medicare contractors as Local Coverage Determinations (LCDs).

Although LCDs shouldn't contradict NCDs, they can differ. In the present study, I analyze some factors that could partially account for the differences between NCDs and LCDs.

Using the Medicare Coverage Database from CMS, I searched for differences between NCDs and LCDs in five benefit categories: inpatient hospital services, durable medical devices, diagnostic laboratory tests, physician's services and other diagnostic tests.

There is a reasonable degree of homogeneity in coverage policies for procedures for which an NCD has been issued: 82% are exactly the same. Most of the differences took the form of exclusions from LCDs, but not from NCDs.

For each state, I computed the number of times that LCDs were issued and the number of times that LCDs differed from NCDs and searched for possible linear or exponential correlation models. The following factors were initially hypothesized to account for these differences: number of Schools of Medicine, number of physicians, GDP per capita by state, state ranking according to number of Level 1 and Level 2 Trauma Centers and the profile of MEDCAC members.

At a national level, I found no correlation between the number of LCDs issued or the number of differences between LCDs and NCDs and any of these variables. However, on a sub-analysis at a local level, in some regions I found a positive correlation ($r^2 > .94$) between the following three variables: 1) number of Schools of Medicine, 2) number of physicians, and 3) state ranking according to the number of Level 1 and Level 2 Trauma Centers and the following two parameters: 1) the level of LCD issuing activity, and 2) the number of times that LCDs differ from NCDs.

The correlations shown by the performed sub-analysis within regions may imply that more LCDs are issued to restrict coverage when there is a local need to control the excessive demand partially driven by the higher number of hospitals and physicians that are active in pursuing their interests. The fact that these correlations were shown only at a regional level may indicate that when local factors are disregarded, the original hypothesized factors do influence LCD activity, however, at a national level, other hypothetical local factors may have a greater influence on LCD activity and policy discrepancies.

In order to have a better understanding of my results and the factors that could account for the differences between NCDs and LCDs, I interviewed four Contractor Medical Directors (CMDs). These interviews indicated that other factors could account for these differences, including the following: a history of abuse and fraud, contractor's budgets, the CMD's special interests and experience, data analysis capabilities, the number of claims and the novelty of the procedure. The impact of these variables on the differences between national and local coverage policies can be an interesting topic for future research on the subject.

To my wife Luisa: thanks for your infinite love and daily support;

to my parents, Norah and Rafael, who have nurtured me with a great education, human values and love; and

to the ones, alive or passed away, who have influenced my thinking and passion for science through their ideas and courage to search for the truth.

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I. Introduction

Reimbursement is often cited by healthcare entrepreneurs, investors and managers as a key factor for the success or failure of adoption of medical technologies. In terms of value creation, reimbursement is more important for medical devices and diagnostics for which FDA approval usually represents a lower risk than pharmaceuticals or biologics. Manufacturers of medical technologies often report that Medicare is the most influential payer not only in terms of market power but also in its influence on other payer's coverage policies. In the same way, positive coverage decisions by the largest and most influential private payers can also influence decisions from other private payers.

Research Objectives

In some cases, Medicare or its contractors issue coverage policies to determine if a specific procedure or medical technology will receive reimbursement and under which circumstances. These policies can be stated at a national or at a local level.

National Coverage Determinations (NCDs) are policies developed by the Centers for Medicare and Medicaid Services (CMS) to direct the nationwide conditions for Medicare coverage for a specific item or service. The decision is usually made at CMS Staff discretion based on benefit categories and statutory exclusions previously defined by the Social Security Act and on an assessment of whether the service or item is reasonable and necessary. For some services, CMS bases its decisions on Technology Assessments (TAs) or on the judgment of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).

On the other hand, Local Coverage Determinations (LCDs) are coverage policies developed by Medicare contractors to decide whether to cover a particular service in their jurisdiction. They can be developed in the absence of an NCD or as a supplement to an NCD as long as the LCD policy does not conflict with national policy. The contractor makes the decision based on an assessment of whether the service is reasonable or necessary. LCDs are more specific administrative and educational tools to assist providers in submitting correct claims for payment, including the acceptable billing codes, which usually are not mentioned in NCDs because they are broader in scope. The vast majority of coverage policies are developed by contractors locally. Sometimes NCDs are released after various LCDs have been issued for the same service by different contractors, indicating the necessity to regulate

coverage at a national level. This is the reason why there are more than five thousand LCDs and only 314 NCDs currently in effect. LCDs are used as a way to implement automated review for those circumstances under which coverage for a service will always be denied. LCDs take significantly less time than NCDs to develop (approximately 4 months vs 9-12 months), particularly if NCDs require TAs or MEDCACs.

According to CMS, LCDs shouldn't contradict NCDs, but in reality they present some differences, although not strictly contradictions. The ultimate aim of this research is to describe the factors that account for the differences between local and national coverage determinations of medical procedures in the US.

Significance, utility and implications of this research

The present thesis will be relevant for any person interested in the US health care industry. It will help policy makers and payers understand the drivers of coverage disparities between different US regions or states, to propose new administrative or policy tools that improve their cost, effectiveness, quality, uniformity and accessibility standards. It will help health technology entrepreneurs, investors and managers by shedding light on the factors that have to be taken into account in order to obtain more favorable reimbursement. For the general population, this study will help to explain the variables that account for the difference in coverage decisions and policies, for insurance purchasing or other purposes.

Background

Medicare Coverage Decisions

With a 2010 budget of approximately \$460 billion and serving nearly 46 million beneficiaries, the Centers for Medicare & Medicaid Services (CMS) are a key player in the US health care system. CMS defines coverage, coding, and payment processes and how they relate to each other. Payment for many new medical technologies can be made under one of Medicare's payment methodologies without being preceded by an explicit coverage determination, coding change, and/or payment decision by CMS. However, the Agency will specifically evaluate issues involving coverage, coding, and/or payment with respect to certain technologies. According to the CMS Innovator's Guide to Navigating Medicare (Version 2.0, 2010), the basic analytical framework that CMS uses for each of these issues is as follows:

1) Coverage

Medicare's authority to cover or exclude certain items or services is governed by the Social Security Act (the Act) and implementing regulations.

Benefit Category – Does the new technology fall into at least one defined benefit category or categories under the Act?

Statutory Exclusion – Does the new technology involve an item or service that is specifically excluded by the Act?

Reasonable and Necessary – Is the new technology “reasonable and necessary” for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member?

2) Coding

Clinically Different – Are changes in coding needed to accommodate the new technology? In most cases, new items and services are adequately described in existing codes. However, some new technologies may warrant differentiation through the creation of new codes.

3) Payment

Payment System – Which fee-for-service payment system(s) does the new technology fit into (e.g., hospital inpatient prospective payment system, physician fee schedule)?

Payment Amount – If the new technology warrants a new code, how will the payment amount be determined?

Coverageⁱⁱ

Fiscal intermediaries and carriers are legal entities that have contracted with CMS to process Medicare claims for Part A and Part B. In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Under section 911 of the MMA, Congress requires that, between year 2005 and 2011, CMS replace the current fiscal intermediary (FI) and carrier contracts with competitively procured contracts that conform to the Federal Acquisition Regulation (FAR). New contracting entities known as Medicare Administrative Contractors (MACs) will merge Part A and Part B claims processing under a single authority. The provisions contained under section 911 are collectively referred to as Medicare Contracting Reform and its main purpose is to make Medicare's administrative structure more dynamic, competitive and performance-based. Under the new structure, most beneficiaries will have their claims processed by only one contractor, which will be required to develop an integrated and consistent approach to medical coverage across its service area. The full fee-for-service (FFS) program functional environment vision includes functional contractors working with the MACs. The major business functions of the MACs are: claims processing, beneficiary and provider customer service, appeals, provider education, financial management, provider enrollment, reimbursement, payment safeguards and information systems security. They will serve as the providers' primary point-of-contact for enrollment, training on Medicare coverage and billing requirements, and the receipt, processing, and payment of Medicare FFS claims within their respective jurisdictions.

The new contracting reform created new jurisdictions to be administered by the MACs, which were assigned to balance the allocation of workloads (the number of fee-for-service beneficiaries and providers) and promote competitionⁱⁱⁱ. CMS has awarded 19 MACs through a competitive bidding process during the initial implementation phase. These include 15 A/B MACs servicing the majority of all types of providers (both Part A and Part B), and four specialty MACs servicing durable medical equipment suppliers.

The fifteen jurisdictions and its A/B contractors areⁱⁱⁱ:

- Jurisdiction 1 (J1) – American Samoa, California, Guam, Hawaii, Nevada, Northern Mariana Islands- Awarded to Palmetto GBA
- Jurisdiction 2 (J2) - Alaska, Idaho, Oregon, Washington Awarded to National Heritage Insurance Company
- Jurisdiction 3 (J3) - Arizona, Montana, North Dakota, South

Dakota, Utah, Wyoming- Awarded to Noridian Administrative Services

- Jurisdiction 4 (J4) - Colorado, New Mexico, Oklahoma, Texas- Awarded to Trailblazers Health Enterprises
- Jurisdiction 5 (J5) - Iowa, Kansas, Missouri, Nebraska- Awarded to Wisconsin Physician Services Health Insurance Corporation
- Jurisdiction 6 (J6) - Illinois, Minnesota, Wisconsin. Awarded to Noridian Administrative Services, LLC
- Jurisdiction 7 (J7) - Arkansas, Louisiana, Mississippi. Awarded to Pinnacle Business Solutions Inc.
- Jurisdiction 8 (J8) - Indiana, Michigan. Awarded to National Government Services, Inc. On January 26, 2009, a protest against the award was filed. CMS is undertaking corrective action on the award. The legacy fiscal intermediaries and carriers will continue to service the providers in those workloads until further notice.
- Jurisdiction 9 (J9) - Florida, Puerto Rico, United States Virgin Islands. Awarded to First Coast Service Options, Inc.
- Jurisdiction 10 (J10) - Alabama, Georgia, Tennessee. Awarded to Cahaba Government Benefit Administrators, LLC (Cahaba GBA)
- Jurisdiction 11 (J11) - North Carolina, South Carolina, Virginia, West Virginia Awarded to Palmetto Government Benefits Administrator, LLC (Palmetto GBA). On June 1, 2010 CIGNA Government Services filed a protest against the award. The legacy fiscal intermediaries and carriers will continue to service the providers until further notice.
- Jurisdiction 12 (J12) - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania –Awarded to Highmark Medicare Services Inc.
- Jurisdiction 13 (J13) - Connecticut, New York- Awarded to National Government Services
- Jurisdiction 14 (J14) - Maine, Massachusetts, New Hampshire- Awarded to National Heritage Insurance Corporation (NHIC)
- Jurisdiction 15 (J15) - Kentucky, Ohio. Awarded to Highmark Medicare Services, Inc. (HMS). Two protests against the award were filed. CMS is undertaking corrective action on the award. The legacy fiscal intermediaries and carriers will continue to service the providers in those jurisdictions until further notice.

The four jurisdictions for Durable Medical Equipment (DME) Specialty MAC carriers areⁱⁱⁱ:

- Jurisdiction A- Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. Awarded to National Heritage Insurance Company
- Jurisdiction B- Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin. Awarded to AdminaStar Federal
- Jurisdiction C- Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virginia, and West Virginia. Awarded to CIGNA Government Services
- Jurisdiction D- Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Northern Mariana Islands, Oregon, South Dakota, Utah, Washington, and Wyoming. Awarded to Noridian Administrative Services

CMS and its administrative contractors, have the authority to develop coverage determinations for particular items or services or to decide claims on a case-by-case basis. Most coverage policies are developed at a local level by contractors, but sometimes CMS may choose to develop a national coverage policy to ensure that similar claims will be adjudicated under uniform criteria. Coverage policies are more likely to be developed when the item or service produces significant clinical consequences for beneficiaries, when the medical community is divided about the merits of an item or service for a particular population, or when the item or service has a significant impact on the Medicare programⁱ.

A Medicare administrative contractor develops Local Coverage Determinations (LCDs) that apply only within their jurisdictions. Administrative Law Judges (ALJs) consider LCDs but are not bound to follow them. CMS makes National Coverage Determinations (NCDs) that are binding policies for all fiscal intermediaries, carriers, MACs, Quality Improvement Organizations (QIOs), Quality Independent Contractors (QICs), ALJs, and the Medicare Appeals Councilⁱ.

Codingⁱ

Currently, CMS uses the International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) and the Healthcare Common Procedure Coding System (HCPCS) for processing Medicare claims. The updated International Classification of Diseases, 10th Edition (ICD-10) is scheduled for implementation on October 1, 2013. In contrast to coverage decisions, changes to coding systems are made strictly at the national level. New technologies are sometimes adequately described by existing codes. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), contractors can no longer establish local codes, although new technologies are sometimes accommodated by 'not otherwise classified' codes pending determination of a new code assignment.

Paymentⁱ

Payment levels for most of Medicare's fee-for-service payment systems are structured to gradually adjust to the use of a new technology, and in general do not require major modifications. In the end, the relative use of a new technology will be reflected in payments for the service using the technology. However, in certain cases, payment adjustments for new technologies are appropriate. Medicare's inpatient and outpatient prospective payment systems include provisions designed to provide an extra payment amount for certain new technologies, based on whether the new technology represents a substantial clinical improvement relative to existing technologies and meet specific cost thresholds. However, under the outpatient prospective payment system, a service may be assigned to a new technology Ambulatory Payment Classification (APC) group and a new drug may receive "pass-through" payment without demonstrating substantial clinical improvement.

Timing of Policy Decisionsⁱ

Coverage, coding, and payment decisions are not necessarily made in any particular order. Sometimes a new technology manufacturer secures a new code before Medicare coverage, or applies for a new technology hospital inpatient add-on payment before FDA has approved the device, anticipating that FDA will grant approval before CMS makes its coverage decisions. Timelines for Medicare coding, coverage and payment decisions may often span a 12-month period. Local and national coverage decisions are made under statutory timeframes, usually taking between 4 and 12 months. Coding changes are commonly made on an annual basis, while some payment changes may occur quarterly.

National Coverage Determination (NCD)ⁱ

NCDs are developed by CMS to describe the nationwide conditions for Medicare coverage for a specific item or service. NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under section 1862(a)(1) of the Social Security Act or other applicable provisions of the Act. NCDs are issued as program instructions. Once published in a CMS program instruction, an NCD is binding on all Medicare Administrative Contractors (MACs), fiscal intermediaries, carriers, Quality Improvement Organizations (QIOs), Qualified Independent Contractors (QICs), Administrative Law Judges (ALJs), the Medicare Appeals Council and Program Safeguard Contractors (PSCs). Medicare Advantage (Part C) health plans are required to cover all items and services that are offered under Part A and Part B, which comply with NCDs, while Medicare Part D plans are excluded from the requirement of following NCDs.

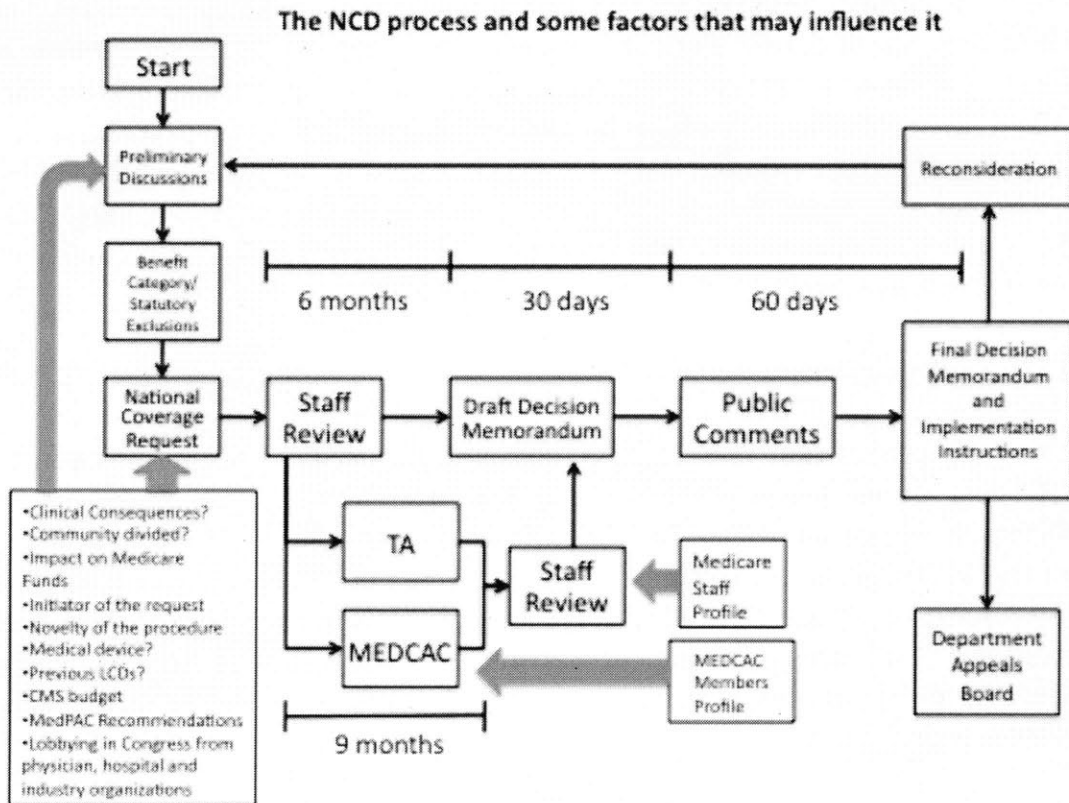
NCD Process^{iiiv}

The NCD process consists of three major steps: initiation, review, and completion. A formal request for an NCD can be initiated either by an outside party or internally by CMS staff. However, CMS formally initiates the NCD process by “opening” the NCD. This is announced to the public by posting a “tracking sheet” on the CMS coverage web site. After that, CMS reviews the particular items and services to determine whether they meet the statutory requirements.

Time frames required for the NCD process are statutory, as mandated by the Medicare Modernization Act (MMA). The time frame does not begin until CMS formally accepts an NCD request. When the volume of formal requests is heavy, CMS may set priorities – reviewing applications for technologies likely to have a greater impact on the Medicare program and its beneficiaries before those with lesser impacts. Once a completed request is accepted, CMS notifies the requester and posts a tracking sheet announcing the NCD review on the CMS coverage website.

For NCD requests not requiring an external technology assessment (TA) or Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) review, CMS must post a proposed decision no later than six months after the date CMS accepts the completed formal request. For NCDs that require either a TA or MEDCAC review, or both, the proposed decision must be posted no later than nine months after the date CMS accepts the completed request.

Before the final decision is reached, CMS staff considers any public comments that may be relevant to the policies. When an NCD currently exists, any individual or entity may request CMS to reconsider any provision of that NCD. The reconsideration request must contain additional medical or scientific information that was not considered during the NCD process or arguments to prove that the NCD misinterpreted the existing evidence. There is also a process by which aggrieved parties may elect to challenge an existing NCD.



Technology Assessmentsⁱ

Technology Assessments (TAs) are systematic reviews, conducted and coordinated by CMS staff to review relevant evidence and inform a determination if the item or service is reasonable and necessary. CMS usually requests TAs when there is conflicting or complex medical and scientific literature available, or when CMS believes an independent analysis of all relevant literature will assist them determine whether an item or procedure is reasonable and necessary^{iv}. To minimize bias, systematic reviews emphasize a comprehensive search of all potentially relevant medical and scientific articles and use explicit, reproducible criteria in the selection of articles for review. Primary research designs and study characteristics are appraised in accordance with a hierarchy of medical evidence. Data are summarized and the evidence is appraised to assess its validity (how credible it is), clinical relevance (its applicability in real health care settings), and weight (magnitude of effect). CMS staff generally performs TAs internally but may contract with an external party to perform a TA.

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)ⁱ

For coverage topics that are highly controversial or have a major potential impact (cost being an important factor) on the Medicare program or its beneficiaries, CMS may draw on the expertise of the MEDCAC. The primary role of the MEDCAC is to provide independent, expert advice to assist CMS in making sound coverage decisions for the topic under review. The MEDCAC reviews and evaluates medical literature and TAs, listens to testimony, deliberates, and provides CMS with recommendations as to the strength of the evidence reviewed.

The MEDCAC is composed of 100 experts in clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics and medical ethics. For each MEDCAC meeting, approximately 15 members are selected with knowledge specific to the topic in question. These can be non-MEDCAC members who have relevant expertise to provide additional input to panel members. The panel meets in a public forum approximately 6 times a year to review medical evidence for the topic under deliberation, listen to public testimony, and provide advice about the quality of the evidence.

Medicare Payment Advisory Commission (MedPAC)^v

The Medicare Payment Advisory Commission (MedPAC) is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the US Congress on issues affecting the Medicare Program. The Commission's statutory mandate is quite broad: in addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

The Commission has 17 members, who have diverse expertise in the financing and delivery of health care services. Commissioners are appointed to three-year terms (subject to renewal) by the Comptroller General and serve part time. Appointments are staggered; the terms of five or six Commissioners expire each year. The Commission is supported by an executive director and a staff of analysts, who typically have backgrounds in economics, health policy, public health or policy.

MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress. In the course of these meetings, Commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties. Commission members and staff also seek input on Medicare issues through frequent meetings with individuals interested in the program, including staff from congressional committees and CMS, health care researchers, health care providers, and beneficiary advocates.

Two reports - issued in March and June each year - are the primary outlet for Commission recommendations. In addition to these reports and others on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

Currently, MedPAC is only an advisory Commission with no formal power to make decisions. However, a 2009 bill introduced by Senator Jay Rockefeller and endorsed by the Obama administration, proposes moving decisions from Congress to MedPAC, turning it into an executive agency. The bill has caused a lot of controversy, because, among other things, it would cease the influence that industry, hospitals and physicians play in policy making through lobbying with members of Congress.

NCD Implementationⁱ

The NCD is the formal instruction to the Medicare claims processing contractors regarding how to process claims (e.g., when to pay, when not to pay, pay only when certain clinical conditions are met). Appropriate payment or other changes to accommodate the coverage decision are effective at the time a final decision is posted to the CMS website. In some instances CMS implements an NCD through the change management process and provides detailed coding and billing instructions. The instructions specify appropriate coding and detail how the NCD criteria are to be implemented in the claims processing systems. Those instructions have a specific effective date dictating when claims will be processed according to the new criteria. The contractors implement the NCD within their own jurisdictions and may subsequently develop LCDs or policy articles to supplement the NCD.

Coverage with Evidence Developmentⁱ

Coverage with Evidence Development (CED) is a coverage decision made through an NCD. These NCDs require additional data collection, such as data collected in a clinical trial, as a condition of coverage. The purpose of CED is to provide Medicare coverage for a particular item or service and to develop evidence of its impact on the health of Medicare beneficiaries. Examples of NCDs that require CED are Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnea and Positron Emission Tomography for Solid Tumors and Myeloma.

Local Coverage Determination (LCD)^{vi}

Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) created and defined the term “local coverage determination” (LCD) as a decision by a contractor whether to cover a particular service on a contractor-wide basis. LCDs may be developed in the absence of an NCD or as a supplement to an NCD as long as the LCD policy does not conflict with national policy. Since Administrative Law Judges (ALJs) are bound by NCDs but not LCDs, simply repeating an NCD as an LCD will cause confusion as to the standing of the policy. Contractors are supposed to apply NCDs when reviewing claims for services addressed by NCDs. The contractor should ensure that all LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

LCDs specify the clinical circumstances under which a service is considered to be reasonable and necessary. They are administrative and educational tools which assist providers in submitting correct claims for payment and guide the medical community and others within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. Contractors educate the provider community on new or significantly revised LCDs through such things as training sessions, speaking at meetings or writing articles in the newsletters.

Medicare contractors previously developed Local Medical Review Policies (LMRPs) as vehicles for local policy. In 2003, CMS instructed the contractors to create LCDs and convert all LMRPs into LCDs. The difference between LMRPs and LCDs is that LCDs consist of only “reasonable and necessary” information, while LMRPs may also have contained benefit category and statutory exclusion provisions. Therefore, CMS further instructed that all other guidance from contractors should be published in a contractor article.

Codes describing what is covered and what is not covered can be part of the LCD. This includes lists of HCPCs codes that spell out which services the LCD applies to, lists of ICD-9-CM codes for which the service is covered, lists of ICD-9 codes for which the service is not considered reasonable and necessary, etc. These coding descriptions are only included if they are integral to the discussion of medical necessity. However, coding guidelines are not elements of LCDs and Medicare states that they should be deleted from the LCDs and instead published in articles.

When a new or revised LCD is needed, contractors do the following:

- Contact the CMD facilitation contractor, other contractors, the local carrier or intermediary, the Durable Medical Equipment Regional Carrier (DMERC) (if applicable), the Medicare Coverage Database or QIOs to inquire if a policy which addresses the issue in question already exists;
- Adopt or adapt an existing LCD, if possible; or
- Develop a policy if no policy exists or an existing policy cannot be adapted to the specific situation.

A contractor with LCD jurisdiction for two or more states is strongly encouraged by CMS to develop uniform LCDs across all its jurisdictions. To ensure that all LCDs remain accurate and up-to-date at all times, at least annually, contractors review and revise LCDs based upon CMS NCDs,

coverage provisions in interpretive manuals, national payment policies and national coding policies.

Contractors may review claims on either a prepayment or post-payment basis regardless of whether an NCD, coverage provision in an interpretive manual, or LCD exists for that service. However, automated denials can be made only when a clear policy exists. The use of an LCD helps avoid situations in which claims are paid or denied without a provider having a full understanding of the basis for payment and denial. In this way, contractors develop LCDs when they have identified a service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review.

Contractors have the option to develop LCDs when any of the following occur:

- A validated widespread problem demonstrates a significant risk to the Medicare trust funds (identified or potentially high dollar and/or high volume services). Multi-state contractors may develop uniform LCDs across all its jurisdictions even if data analysis indicates that the problem exists only in one state.
- An LCD is needed to assure beneficiary access to care.
- A contractor has assumed the LCD development workload of another contractor and is undertaking an initiative to create uniform LCDs across its multiple jurisdictions; or is a multi-state contractor undertaking an initiative to create uniform LCDs across its jurisdiction.
- Frequent denials are issued (following routine or complex review) or frequent denials are anticipated.

According to CMS, LCDs are supposed to be clear, concise, properly formatted and not restrict or conflict with NCDs or coverage provisions in interpretive manuals. Coverage provisions in interpretive manuals are instructions that are used to further define when and under what circumstances services may be covered (or not covered). If an NCD or coverage provision in an interpretive manual states that a given item is "covered for diagnoses/conditions A, B and C," contractors are not supposed to use that as a basis to develop LCDs to cover **only** "diagnoses/conditions A, B and C." When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors usually allow for individual consideration unless the LCD supports automatic denial for some or all of those other diagnoses/conditions.

In order to be covered under Medicare, a service shall be reasonable and necessary. According to the CMS Manual System, contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition; or
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

LCDs are based on the strongest evidence available. The initial action in gathering evidence to support LCDs has to be always a search of published scientific literature for any available evidence pertaining to the item/service in question. In order of preference, LCDs are based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts.

Contractors sometimes implement new Least Costly Alternative (LCA) determinations through an LCD. "Least Costly Alternative" is a national policy provision that is applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply

this principle to payment for non-DME services as well. When strong clinical justification exists, contractors may also develop LCDs that contain absolute words such as "is never covered" or "is only covered for". When phrases with absolute words are clearly stated in LCDs, contractors are not required to make any exceptions or give individual consideration based on evidence. Contractors create edits/parameters that are as specific and narrow as possible to separate cases that can be automatically denied from those requiring individual review.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. LCDs that challenge the standard of practice in a community and specify that an item is never 'reasonable and necessary', should be based on sufficient evidence to convincingly refute evidence presented in support of coverage. Less stringent evidence is needed when allowing for individual consideration or when the used criterion is the least costly alternative.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), section 731, requires the Centers for Medicare & Medicaid Services (CMS) to develop a plan to evaluate new LCDs to decide which local decisions should be adopted nationally. CMS currently has policies in place that address the MMA requirements to promote greater consistency among LCDs, require Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on LCDs among Medicare contractors.

When assessing whether an LCD topic should be referred to the 731 Advisory Group for NCD consideration, contractors consider the following criteria:

- Net impact on clinical health outcomes;
- Current and projected local utilization patterns outside of perceived reasonable and necessary boundaries;
- Current and projected national utilization patterns outside of perceived reasonable and necessary boundaries;
- Unit cost;
- Collateral costs;
- Associated quality and access to care issues including capacity of health system to use technology safely; and
- Medicare payment error rate impact.

The Carrier Advisory Committee (CAC)^{vi}

Carriers usually establish one CAC per state. Where there is more than one carrier in a state, the carriers jointly establish a CAC. If there is one carrier for many states, each state has a full committee and the opportunity to discuss draft LCDs and issues presented in their state. Carriers that develop identical policies for their entire jurisdiction may sometimes establish a single CAC. A contractor with LCD jurisdiction for two or more states is strongly encouraged to develop uniform LCDs across all its jurisdictions.

The purpose of the CAC is to provide:

- A formal mechanism for physicians in the state to be informed of and participate in the development of an LCD in an advisory capacity;
- A mechanism to discuss and improve administrative policies that are within carrier discretion; and
- A forum for information exchange between carriers and physicians.

While the CAC reviews all draft LCDs, the final implementation decision about LCDs rests with the Contractor Medical Director (CMD).

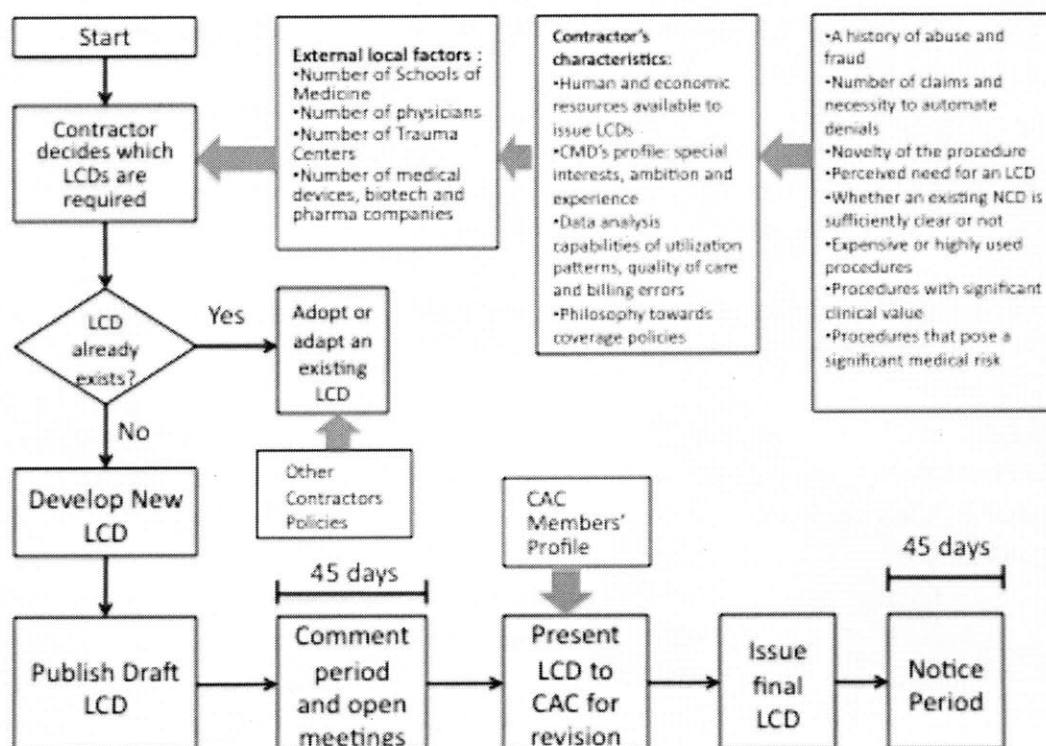
The CAC is to be composed of physicians, a beneficiary representative, and representatives of other medical organizations. CAC members serve to improve the relations and communication between Medicare and the physician community. Specifically, they:

- Disseminate proposed LCDs to colleagues in their respective state and specialty societies to solicit comments;
- Disseminate information about the Medicare program obtained at CAC meetings to their respective state and specialty societies; and
- Discuss inconsistent or conflicting policies.

Each specialty has one member and a designated alternate with approval of committee co-chairs. Additional members sometimes attend when policies that require their expertise are under discussion. The CAC is co-chaired by the CMD and one physician selected by the committee. Co-chairs present all proposed LCDs to the CAC for discussion. The CAC holds a minimum of 3 meetings a year, with no more than 4 months between meetings. Each meeting should include a discussion and presentation of comparative utilization data that has undergone preliminary analysis by the carrier and

relates to discussion of the proposed LCD. Carriers solicit input from CAC members to help explain or interpret the data and give advice on how overutilization should be addressed. Sometimes the Committee uses data to illustrate the extent of problem billing (e.g., average number of services per 100 patients) to help justify the need for a particular policy. Participation in the CAC is considered a service to physician colleagues. Carriers do not provide an honorarium or other forms of compensation to members. Expenses are the responsibility of the individuals or the associations they represent.

The LCD process and some factors that may influence it



Local Coverage Determination Time Framesⁱ

Unlike the NCD time clock that begins with the acceptance of a formal request to open an NCD, the time clock for an LCD begins with the initiation of a minimum 45-day comment period following publication of a draft LCD. During this time, comments on the draft LCD must be solicited from several outside parties, including affected health professionals, other contractors,

providers, and QIOs. In addition to the draft LCD comment period, contractors provide open meetings for the purpose of discussing draft LCDs prior to presenting the policy to the Contractor Advisory Committee (CAC). Once the contractor has considered all the comments and developed the final LCD, it must be published on Medicare's coverage website. A minimum notice period of 45 days is required prior to the effective date of implementation.

Principal differences between NCDs and LCDs

	NCD	LCD
Developed by	CMS	Contractors
Geographical applicability	Nation-wide	Contractor-wide
Binding to	MACs, Fis, Carriers, QIOs, QICs, ALJs, PSCs and Medicare Appeals Council	MAC Jurisdiction
Not binding to	Medicare Part D plans	ALJs
Process initiated internally or externally	Both	Internally, by the MACs
Process open to the public?	Yes	Yes
Time to complete	9-12 months after NCD is accepted, statutory	45 days after draft LCD is issued and 45 days of notice period before it is effective. Total process takes about 4 months
Base of decision	CMS Staff Review and sometimes TAs and MEDCACs	Medical literature, CMS, other contractors and CACs
Contains applicable codes?	No	Yes
Conditions and limitations	More general	More restrictive
Number of policies currently in effect published in CMS website	314	More than 5'000

Private payers coverage decisions

The private US health care system works mainly through employer-based insurance contracted either through traditional indemnity insurance or Managed Care Organizations (MCOs). Managed Care refers to a constellation of networks, payment policies, utilization review and other functions wrapped around the traditional insurance function whose goal is to rationalize the care received and reduce its cost. Managed Care Organizations include:

- Health Maintenance Organizations (HMOs), which manage health plans with a closed network of physicians outside of which care is not reimbursed.
- Point of Service (POS) health plans, which is the same as an HMO but with the option to go out of network with substantial additional coverage.
- Preferred Provider Organizations (PPOs), which manage health plans that contract with a network of “preferred” physicians but also offers reduced coverage outside of that network.

Most of the private health in the US is provided by MCOs either directly or because insurers subcontract their services with an MCO. There are hundreds of Managed Care Organizations in the United States and each has different structures and procedures for making coverage decisions. For a technology to be eligible for reimbursement by a Managed Care Organization, usually the technology must not be excluded by the language of the health insurance contract between the MCO and insurers, who are the payers at the end. This generally means that the technology must contribute to provision of one of the broad categories of services specified as being covered (hospital services, physician office visits, durable medical equipment), must be “medically necessary” under the particular circumstances of the case, and must not be “experimental” or “investigational”. In addition, many contracts exclude or limit coverage for various more-or-less specific services. The contractual framework is typically determined through negotiations between purchasers (employers) and MCOs. Within this framework, MCO personnel, such as a medical director and utilization review staff, interpret contracts to make decisions about coverage and payment for emerging technologies^{vii}.

Sometimes an MCO undertakes a formal process to determine whether a technology should be covered under any circumstance. Such decisions can require judgments about whether the technology pertains to a covered benefit or is investigational, or about the conditions under which its use is safe and effective. Many of these issues can be informed by a Technology

Assessment (TA), which is a somewhat structured effort to judge the clinical effectiveness and sometimes the cost-effectiveness of medical technologies, similar to Medicare TAs. It usually involves critical evaluation and synthesis of evidence available from clinical studies and other systematic evidence; often, expert opinion is incorporated. On top of peer-reviewed journals, local academics and physicians leaders, MCOs often obtain assessments from public and private organizations like the Health Care Financing Administration (HCFA), the Agency of Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), the Emergency Care Research Institute (ECRI), Hayes Inc. and the Blue Cross, Blue Shield Technology Institute for Health Care Management Research and Educational Foundation. If medical directors, committees, or other staff determines that a technology is covered, patient-selection criteria are often developed. These criteria specify the circumstances under which use of the technology is viewed as medically necessary. On medical necessity determinations sometimes it is difficult to distinguish between medical factors such as mortality, and non-medical factors, like quality of life and convenience^{vii}.

Formal TAs are typically performed by large payers, which usually have several affiliated health plans operating in various locations; however, a positive coverage decision by one of these large MCOs does not guarantee coverage by its affiliated plans. Formal coverage decisions may not be crucial to how extensively a new technology is used. Sometimes new technologies are reimbursed without MCO personnel even being aware of that fact, usually because it is being used by a plan's providers and billed under a pre-existing Current Procedural Terminology (CPT) code, so that the bill is paid without anyone within the MCO being aware that a new technology is involved^{vii}.

A positive decision on coverage does not mean that every enrollee has access to the procedure; MCOs have processes for determining whether the procedure is medically necessary in particular cases. These processes are performed at a local level, even if coverage decisions are made nationally. MCOs that provide care through contracts with capitated medical groups may delegate medical-necessity decisions to them. This is because capitated medical groups bear the financial risk by accepting a flat fee to provide covered benefits to a specific group of individuals^{vii}.

MCOs generally lack systematic surveillance mechanisms for new technologies. They tend to react to triggers such as physician and patient demand, prior-authorization requests and claims submitted without a CPT code. MCOs also base their coverage decisions on their competitor's decisions. When several of their physicians report receiving payment from one of their

competitors, an MCO is likely to assess whether it should cover the procedure. The importance of MCOs has grown in the last two decades due to concerns of increased cost. MCOs have different degrees to which they -or their providers- bear the financial risk for use of some procedures or medical technologies^{vii}.

MCOs also consider nonmedical factors in making coverage decisions, including^{vii}:

- State insurance mandates and other state regulatory requirements
- Publicity about and controversy surrounding a procedure or medical device
- Demand for a technology among patients and physicians
- Potential for litigation

Denials of coverage can be difficult in cases of life-threatening illnesses in which patients have the right to appeal for denial of coverage. Typically, indemnity insurers are more willing to cover some procedures and in many cases, they reimburse more generously^{vii}.

II. Hypothesis

The hypothesis of the present research is that disparities between local and national coverage policies are influenced in a statistically significant manner at the state level by the following variables:

- Number of Schools of Medicine;
- Number of physicians;
- Gross Domestic Product (GDP) per capita by state, which is the state's economic output divided by its number of inhabitants (also called Gross State Product per capita);
- State Ranking according to number of Level 1 and Level 2 Trauma Centers + Population density per square mile;
- MEDCAC member's characteristics.

We would expect the correlations to be as follows:

Negatively Correlated Variables:

- Number of Schools of Medicine and number of physicians: Because LCDs are usually more restrictive than NCDs, and don't contradict them, an LCD tends to restrict physician's ability to use new tools and therefore would be against their interests. The more medical schools there are, the more active physicians there would be to advocate for their interests, which would be reflected in less discrepancies between LCDs and NCDs and less LCD issuing activity.
- GDP per capita per state. In a similar way, a higher GDP per capita is expected to be correlated with a more inclusive coverage policy, which would be reflected in less discrepancy between LCDs and NCDs and less LCDs issued. The reasoning here is that greater purchasing power usually leads to higher consumption levels for health care services.
- State Ranking according to number of Level 1 and Level 2 Trauma Centers, adjusted for population density. A better ranking in number of Level 1 and Level 2 Trauma Centers (which means a lower number in the ranking) is also expected to be correlated with a more inclusive coverage policy (less discrepancy between LCDs and NCDs and less issued LCDs), because more sophisticated Medical Centers have a wider offering of health services and advocate for their reimbursement.

Finally, for procedures that require a MEDCAC to make a decision, it is expected that the MEDCAC composition will influence the number and characteristics of issued LCDs, according to the MEDCAC's member's profile.

III. Research methods

Data

The Centers for Medicare and Medicaid Services (CMS) have a Medicare Coverage Database accessible by the Internet at <http://www.cms.gov/mcd>. Using the Advanced Search option, I found 314 matches for National Coverage Decisions (NCDs) that are currently in effect. From those, I narrowed my search to all NCDs currently in effect in the following benefit categories, which I think are the most important areas in terms of market size for development of health technologies:

- Inpatient Hospital Services
- Durable Medical Devices
- Diagnostic Laboratory Tests
- Physician's Services
- Diagnostic Tests (other)

The previous search narrowed the NCDs to 193 matches. On these matches, I gathered the following information to assemble a database for this research purposes:

- National Coverage Determination (NCD) section
- NCD title
- Implementation date
- National Decision (Covered=1 or Not Covered=0)
- National Coverage Limitations
- Technology Assessment (TA) (0=no TA to make decision, 1=TA)
- MEDCAC (0= no MEDCAC required, 1=MEDCAC required)
- Local Coverage Determination (LCD) number
- Contractor
- Contractor Type
 - FI=Fiscal intermediary
 - Carrier
 - MAC Part A=Medicare Administrative Contractor Part A
 - MAC Part B=Medicare Administrative Contractor Part B
 - DME MAC= Durable Medical Equipment Medicare Administrative Contractor

- RHHI= Regional Home Health and Hospice Intermediary
- State where LCD is applicable
- Effective date of LCD
- Local Coverage Decision (0=Not covered, 1=Covered)
- Local Coverage limitations
- Difference of Coverage Limitations between NCD and LCD (0=Different, 1= the same)
- Difference of Coverage Limitations between different states (0=at least one state has a different policy, 1=all states have the same policy)
- Base of Decision (Journals, CMS, specific sources, etc)

After the previous information was obtained (see Tables 1 to 5), I computed for each state the number of times that LCD Coverage Limitations coincided with their NCD counterparts, the number of times that they were different and the total number of times that a state issued an LCD (see Table 6). For this research purposes, different Coverage Limitations between LCDs and NCDs means there is at least one different criterion for coverage.

As shown in Table 7, I collected the following data for each state from their indicated sources:

- Number of Schools of Medicine, from the Association of American Medical Colleges (AAMC)
- Number of physician's, from the United States Department of Labor, Occupational Employment Statistics, May 2009. It doesn't include self-employed doctors.
- Gross Domestic Product (GDP) per capita by state, from the US Department of Commerce, Bureau of Economic Analysis, 2008
- Number of Level 1 and Level 2 Trauma Centers, from DataMasher (www.datamasher.org)
- Population density per square mile, from DataMasher (www.datamasher.org)
- Number of Level 1 and Level 2 Trauma Centers + Population density per square mile, from DataMasher (www.datamasher.org)
- State Ranking according to Number of Level 1 and Level 2 Trauma Centers + Population density per square mile, from DataMasher (www.datamasher.org)

Once I assembled the database I used the Excel LINEST, LOGEST and PEARSON functions to find possible linear or exponential correlation models

and the Pearson product-moment correlation coefficient between various pairs of variables for each State. The pairs of variables I analyzed were:

- Number of times an LCD differed from an NCD versus:
 - Number of schools of medicine
 - Number of physicians
 - GDP per capita
 - Ranking according to number of Level 1 and 2 Trauma Centers adjusted for population density
- Number of times an LCD was the same as an NCD versus:
 - Number of schools of medicine
 - Number of physicians
 - GDP per capita
 - Ranking according to number of Level 1 and 2 Trauma Centers adjusted for population density
- Total number of times an LCD was issued versus:
 - Number of schools of medicine
 - Number of physicians
 - GDP per capita
 - Ranking according to number of Level 1 and 2 Trauma Centers adjusted for population density

I quantified the number of times an LCD was the same as an NCD because it is not exactly the difference between the total LCDs and the number of times an LCD differed from NCDs, since for some procedures the difference couldn't be determined due to lack of information. On the other hand, although the total number of times an LCD was issued was expected to be highly correlated with the number of times an LCD differed from an NCD, I measured its correlation with the chosen variables separately because it may not always be the case.

To analyze the MEDCAC members characteristics, first I downloaded the members list from the CMS website at https://www.cms.gov/FACA/02_MedCAC.asp, under the archive "Roster" (updated 05/05/2010). The list includes name, academic grades, occupation and organization affiliation. I gathered the following information from various Internet public sources:

- Specialty
- Age (In some cases, it was available at www.healthgrades.com or it was approximated when the number of years since graduation was provided)
- State where the organization to which the member is affiliated is located
- Sex

From the MEDCAC database I obtained the Committee profile, according to the members characteristics.

In order to test my conclusions further and to understand more the local and national coverage determination processes and other possible factors that influence them, I interviewed four Contractor Medical Directors (CMDs), who are the key players in the LCD process. The interview questions and responses can be found in Appendix A.

Limitations of the approach

The present research is focused on discrepancies between NCDs and LCDs. It doesn't analyze discrepancies between LCDs. As most of the currently issued policies are LCDs, this research approach fails to assess most of the discrepancies at the local level. However, with the Medicare contractor's consolidation taking place in the last seven years as part of the Medicare Contracting Reform, national policies are gaining importance as means to homogenize the current disparities in coverage. Analyzing discrepancies between local policies, although an interesting exercise, would give a picture of the past state of affairs of coverage policies, instead of the expected future trends.

A second limitation of the present approach is its focus on Medicare coverage policies. The other big player in coverage policies is the private insurance sector. But due to the difficulty in collecting information from the private sector, as well as the chosen limits for this research, the present research study is limited in that regard to the public sector. However, because Medicare coverage policies influence to a great extent coverage decisions of private payers, the present approach is of great importance to understand the system as a whole. Also, private payers are generally happy to rely on Medicare coverage guidelines in developing their own.

Data limitations and challenges

The data necessary for this research were easily accessible from public sources in the Internet, mainly from the CMS website. However, detecting the differences between NCDs and LCDs coverage limitations posed a greater challenge for assembling the database. It meant reading the different national and local policies for 193 procedures, which was very time-consuming and

required a lot of concentration and sometimes a subjective judgment to decide if the difference was real or only in terms of the language used. If at least one coverage criterion or condition was different or additional (usually in the LCD), I defined it as different.

IV. Results

I analyzed a total of 193 procedures with NCDs currently in effect. From these, 137 (71%) received a positive decision, while 56 (29%) denied coverage. Only two procedures, Nesiritide for Treatment of Heart Failure Patients and Lymphocyte Mitogen Response Assays, had a clear difference between the NCD and LCDs. The first procedure was not covered under the NCD while it was covered by the LCDs. For the Mitogen Response Assays the difference in coverage policies was the opposite: covered according to the NCD and not covered by the LCDs. For all other procedures the difference was in the coverage policy and limitations. Usually, LCDs are more specific in their criteria and have more limitations than NCDs. However, having different policies and coverage limitations between NCDs and LCDs doesn't necessarily mean they contradict each other.

From the 193 analyzed procedures, only 69 had issued LCDs, leaving the majority of procedures (nearly two thirds) with a homogeneous coverage policy dictated by the NCD. From the total LCDs issued for these 69 procedures, 51% differ in one way or another from the corresponding NCD, while 46% of the LCDs were exactly the same as the NCD (for 3% of the LCDs, the difference from the NCD couldn't be assessed due to lack of information). From the 193 procedures, only 10 required Technology Assessments and only 12 required MEDCACs as support to make the decision.

The procedures that required Technology Assessments are:

- Acupuncture for fibromyalgia (not covered, no LCD)
- Acupuncture for osteoarthritis (not covered, no LCD)
- Vertebral Artery Surgery (covered, no LCD)
- Fecal Occult Blood Test (covered, LCDs different from NCD)
- Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (covered, no LCD)
- Hyperbaric Oxygen Therapy (covered, LCDs different from NCD)
- Magnetic Resonance Spectroscopy (not covered, LCDs same as NCD)
- Ambulatory Blood Pressure Monitoring (covered, no LCD)
- Computed Tomography (covered, LCDs different from NCD)

The procedures that required a MEDCAC are:

- Bariatric Surgery for Treatment of Morbid Obesity (covered, LCDs different from NCD)
- Percutaneous Transluminal Angioplasty (PTA) (covered, LCDs different from NCD)
- Stem Cell Transplantation (covered, LCDs different from NCD)
- Transmyocardial Revascularization (TMR) (covered, LCD same as NCD)
- Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (covered, LCDs different from NCD)
- Home Blood Glucose Monitors (covered, LCDs different from NCD)
- Noncontact Normothermic Wound Therapy (NNWT) (not covered, LCD different from NCD)
- Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (covered, LCDs different from NCD)
- Ocular Photodynamic Therapy (OPT) (covered, LCD same as NCD)
- Ambulatory Blood Pressure Monitoring (covered, no LCD, also required a TA)
- Positron Emission Tomography (FDG) for Oncologic Conditions (covered, LCD same as NCD)
- Positron Emission Tomography (PET) Scans (under review)

The benefit category with most issued NCDs and LCDs is physician's services, while the benefit category with least issued NCDs and LCDs is laboratory services.

As shown in Table 6, the states with most issued LCDs are (in descending order): Virginia, West Virginia, Illinois, Wisconsin, Ohio, Michigan, Kentucky, Indiana and Connecticut, mostly states from the East Coast and Great Lakes region. The states with the least issued LCDs are (in ascending order): Idaho, Alaska, Arizona, Oregon, Washington, Alabama, Georgia, Minnesota, Mississippi, Tennessee, New Jersey, District of Columbia, Montana, North Dakota, South Dakota, Utah and Wyoming.

The states with the higher number of differences between NCDs and LCDs are (in descending order): Virginia, West Virginia, Ohio, Kentucky, Illinois, Michigan, Kansas, Indiana, Connecticut and New York. The states with the higher number of equal policies between NCDs and LCDs are (in descending order): Virginia, Virgin Islands, Florida, Illinois, Michigan, North Carolina, Wisconsin, West Virginia, Ohio, Kentucky, South Carolina, Indiana and Connecticut.

Most states that are very active in producing LCDs also have a high number of both, policies that differ from NCDs and policies that are the same as NCDs. Kansas and New York are average states with respect to producing LCDs but they have high rates of discrepancies between NCDs and LCDs. On the other hand, Florida, the Virgin Islands, North Carolina and South Carolina are also average states with respect to LCD issuing activity but most of their local policies are equal to NCDs.

I also analyzed whether there is a pattern of association between the previous LCDs results and Medicare Part A and Part B contractors. As shown in table 11, I only found a possible link between the states with the least issued LCDs and their respective contractors. From 17 states, six (Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming) receive administrative service for Medicare Part A and Part B by Noridian Administrative Services, while four states (Idaho, Alaska, Oregon and Washington) are serviced by the National Heritage Insurance Company. However, these two contractors also service other states that don't have a low LCD activity. Based on this preliminary analysis, LCD activity and discrepancies with NCDs don't appear to be related to the jurisdiction or contractor to which the states belongs, but further research would be needed to study a possible link.

The linear and exponential correlation models between the various pairs of variables that I analyzed for each state didn't demonstrate any significant relationship between any of these variables (see Table 8). For both the linear and the exponential models, the coefficient of determination (r^2), which is the square of the correlation coefficient between the two variables, had a very low value (less than 0.15), indicating a very poor description of the correlation of the two variables with the models used. The Pearson product-moment correlation coefficient is a measure of the strength of the linear correlation between the two variables. It is obtained by dividing the covariance of the two variables by the product of their standard deviations. For all the pairs of variables analyzed, the Pearson product-moment correlation coefficient had a very low value indicating a very weak correlation between them.

Sub-analysis

To search further for possible correlation patterns, I narrowed my analysis to representative states from three strategic geographical areas: the East Coast, the Center and the West Coast. I performed the same statistical analysis for the following states: Massachusetts, New York, Maryland, Georgia, Florida,

Illinois, Missouri, Texas, California, Oregon and Washington. The states and regions for the sub-analysis were chosen based on their relevance in terms of number of patients and health care industrial and regulation activity. There wasn't any significant correlation between the same pair of variables for these states (see Table 9).

To find possible disparities drivers between regions, I divided the previous states in their respective regions as follows:

East Coast:

Massachusetts
New York
Maryland
Georgia
Florida

Center:

Illinois
Missouri
Texas

West Coast:

California
Oregon
Washington

I performed the same statistical analysis between regions, taking average values for each region, to correct for the difference in the number of states from each one (see Table 9). I found that the number of Medical Schools and the state's ranking according to the number of Level 1 and 2 Trauma Centers (adjusted for population density) are positively correlated with the number of LCDs that are different from NCDs, the number of LCDs that are the same as NCDs and the total number of issued LCDs. As the number of Medical Schools increases and the ranking is better (lower ranking number), the total number of issued LCDs increases, including the ones that are different from NCDs and the ones that are the same. These correlations are best explained by an exponential model, with $r^2 > 0.94$.

I also performed the same statistical analysis within each region, to see if there were any significant correlations between the same variables when comparing states of the same region (see table 9). In the East Coast, I didn't find any significant correlation. In the Central US, there was a correlation between the state's ranking according to the number of Level 1 and 2 Trauma Centers (adjusted for population density) and the number of LCDs differ from

NCDs and the total number of issued LCDs. The better the ranking (lower ranking number), the greater the number of LCDs which differed from NCDs, and the more LCDs were issued. These correlations were very well explained by both linear and exponential models, with $r^2 > 0.95$. Finally, in the West Coast, I found that the number of Schools of Medicine and the number of physicians are positively correlated with the number of LCDs that are different from NCDs and the total number of issued LCDs. As the number of Schools of Medicine and physicians increases, LCDs that are different from NCDs and total issued NCDs also increase. Both correlations were very well explained by linear and exponential models, with $r^2 > 0.99$.

MEDCAC Members Analysis

The MEDCAC analysis shows the following characteristics of its current members, shown in Table 10:

Professional profile. 69% of the members hold Medical Doctor (MD) degrees, 20% have a PhD, 11% a Master of Science, 11% a Master of Public Health and 10% hold a Master of Business Administrations (MBA). There are only 4 Registered Nurses in the Committee and 3 members with a JD degree. With the exception of one MD member that is a general practitioner, all the other MDs are specialists. The main specialties are, in descending order:

- Internal medicine (12 members)
- Cardiology (7)
- Pathology (4)
- Anesthesiology, emergency medicine, orthopedic surgery, geriatrics, surgery, neurology, ophthalmology, pharmacology, family medicine, epidemiology, gastroenterology and immunology (3 members each).

The following specialties are not represented in the Committee:

- Obstetrics/Gynecology
- Intensive care medicine
- Oral/maxillofacial surgery
- Otolaryngology
- Dermatology
- Pediatrics
- Pulmonology
- Rheumatology

Although for each MEDCAC meeting 15 additional members (which can be non-MEDCAC members) are selected with knowledge specific to the

topic in question to provide additional input, the absence of permanent members that represent very important specialties such as obstetrics/gynecology, dermatology, pediatrics and pulmonology is very notable.

Age profile. I could obtain or approximate the age for 1/3 of the members, with an average age of 53 years.

Sex profile. 67% of members are men.

Geographical profile. The data shows the prominence of some states on which most of the members work. In descending order, these are: Illinois, Massachusetts, New York, California, Pennsylvania, Michigan, New Jersey, Connecticut, Florida, Washington, Ohio, Georgia, District of Columbia, Maryland and Minnesota. The data shows most members are concentrated in the East Coast and the Great Lakes area.

Academics vs non-academics. 78% of members are academics while 22% are non-academics.

Academia versus industry. 59% of the members work in academic institutions, while 41% work in industry.

Patient advocates and industry representatives. There are 6 members representing patient advocate organizations and 6 members representing industry, of which two are from Pfizer.

Contractor Medical Directors (CMDs) Interviews

The following is a summary of the main opinions shared by most of the CMDs interviewed:

There is not a direct correlation between the time frames for issuing NCDs and LCDs. Some LCDs are issued without any NCD preceding them and later an NCD is issued for the procedure, after many LCDs have made clear the necessity for an NCD. Sometimes NCDs are issued without any LCD previously in place and LCDs come later to adapt it to the specific coverage circumstances of the contractor. The main reason to issue an LCD after an NCD is already in place is to specify the billing codes that apply according to the contractor's criteria. NCDs don't specify billing codes, because CMS doesn't have the human and economic resources necessary to do it.

Consistency between LCDs from different contractors is required only for the four DME contractors (due to their limited number it is relatively easy for them to agree on coverage policies). For other benefit categories, consistency is harder to achieve. One CMD mentioned that the original idea of CMS wasn't to achieve consistency between different contractors but to let them adapt policies to the local standards of medical practice. But today, with evidence-based medicine, there is no reason to have variation between medical practice across states, so LCDs should be consistent across contractors.

CMDs made very clear that LCDs shouldn't contradict NCDs. However, they recognize that LCDs present differences from NCDs, mainly in the form of exclusions not specified in NCDs. These exclusions are specified through billing codes applicable for LCDs. CMS intentionally leaves these exclusion decisions open to the contractor's discretion. These exclusions are supposed to be adaptations of the NCD to local circumstances, like detected local aberrant billing patterns and local standards of medical practice. Using the exclusions specified in LCDs streamline the denial of claims, decreasing the need for assessing claims one by one, which is more costly for contractors than issuing an LCD.

The following were mentioned as drivers of LCD issuing activity:

- The necessity to automate legitimate denials
- A history of abuse and fraud for the procedure or in the geographical area
- The CMD's special interests according to his/her specialty
- Human and economic resources available to issue LCDs
- When there are new procedures, to make clear coverage conditions
- Contractor's philosophy towards coverage policies. Some contractors prefer to leave coverage decisions in the hands of physicians, while others have a different approach to coverage decisions.
- How clear is the NCD. If it is sufficiently clear, contractors have less need to issue an LCD.
- Perceived need for an LCD, which can depend on the population density and the number of Trauma Centers, physicians and Schools of Medicine.
- Ambition and experience of the CMD. More experienced CMDs issue more LCDs
- Data analysis of medical necessity criteria based on:

- Quality of care
- History of claim's billing errors
- Billing abuse
- Historical problematic areas
- Comparison of utilization patterns between states

The decision to issue an LCD rests in the CMD. Although the CAC has only an advisory role, its composition and level of activity and expertise of its members influence the LCD process. Usually, CAC members are proposed by the local medical associations. CACs meet approximately every four months, reviewing 6 to 8 LCDs in two hours, with approximately 30 physicians from the specialties impacted by the particular LCDs discussed in each meeting. Each LCD takes about 90 days to complete. According to one CMD, because joining a CAC is not compensated or reimbursed, it requires time and often money from the physicians, making it difficult to recruit opinion leaders. For this and other reasons, CMDs without enough staff or efficient CACs often copy other contractor's LCDs. In the future most CMDs interviewed think contractors will end up with one CAC per jurisdiction.

The CMDs prioritize LCDs to issue according to the following criteria:

- Data analysis of medical review;
- New technologies that might pose a risk to the Medicare funds;
- Procedures with perceived overutilization;
- Procedures where there is concern for abuse;
- The number and type of claims received;
- Procedures that are expensive or very highly used;
- Procedures that have a significant clinical value or that pose a significant medical risk.

Situations can arise where there are LCDs issued for some, but not all states in a jurisdiction because some of the LCDs have been issued by different contractors before Medicare Contracting Reform. But once contractor consolidation takes place, contractors should issue LCDs for all states in their jurisdiction.

Medicare Contracting Reform will cause more homogeneous policies between states due to the decreasing number of contractors, but there will still be differences between states belonging to different contractors. There will no longer be differences between Medicare Part A and Part B policies because they will be issued by the same contractor.

When an LCD challenges the standard of practice, there is pressure from the profession, industry and consumers to change it. If other contractors cover the procedure, the pressure to change the LCD will be higher. This political pressure can push the contractor to put the LCD on hold. However, if the decision is based on clinical evidence from respected journals or expert opinion, it will prevail.

The Least Costly Alternative (LCA) coverage criterion is not used anymore even for DMEs due to a recent court decision (Hays vs. Sebelius) and legal pressure from the medical device and pharmaceutical industries.

Most NCDs are not based on TAs or MEDCACs because they are costly to CMS and because many NCDs are not issued for new technologies, which are more prone to require TAs or MEDCACs. According to one CMD, procedures that require medical devices (as opposed to drugs) are more subject to NCDs where TAs or MEDCACs are used, since the FDA approval for medical devices can be less stringent than that for drugs, and may assess the safety of the device more than its clinical value. Thus, further clinical evidence is needed to justify coverage, and this is usually based on TAs or MEDCACs. This was confirmed by my analysis, which shows that of the 22 procedures requiring TAs or MEDCACs, 14 involve medical devices.

A lot of policy activity is carried on at the local level because contractors issue LCDs faster than CMS issues NCDs and because CMS doesn't have the resources to make all policy decisions. However, the level of expertise and structure of the evaluation mechanism are lower at the local level. One CMD mentioned that the medical device and pharmaceutical industries prefer to convince local contractors of the benefits of their technologies at the local level instead of CMS, because it is easier in terms of the evidence required and time invested. Once a contractor issues a policy in favor of the procedure, other contractors are pressured to do the same.

V. Discussion of results

The present discussion of results is based on an analysis of 193 (61%) procedures from 314 with NCDs currently in effect.

LCDs agree, with the exception of very few decisions (2 from 193), with NCDs in the ultimate question they are trying to address: is the procedure covered? However, a more meticulous analysis reveals that approximately half (51%) of LCDs differ from NCDs in the conditions, circumstances and specific criteria that set the limits of that coverage decision. The main difference between NCDs and LCDs is in the form of exclusions specified in LCDs through applicable billing codes that are not specified in NCDs. CMS intentionally leaves these exclusion decisions open to the contractor's discretion to adapt the NCDs to their local needs and because CMS doesn't have the resources and speed to manage all this policy activity. States that don't issue LCDs have to adhere to the respective NCD. 64% of procedures (124/193) that have an NCD don't have any LCD at all. According to CMDs, this could mean that most NCDs are sufficiently clear and don't require specific billing coding information or that any of the other drivers of LCD issuing activity are usually absent (aberrant billing patterns, new procedures, etc.). If we take into account that from 193 procedures that have NCDs only 69 (36%) have at least one LCD and that from these, 46% are exactly the same as their NCDs counterparts (while 51% are different), only 18% ($69/193 \times 0.51$) of procedures have local policies that are to some extent different from the national policies. This means there is a reasonable degree of homogeneity in coverage policies (82%) across the United States for procedures for which an NCD has been issued. However, most procedures have LCDs without an NCD in place, in which case the differences in coverage policies depend on the degree of variability between LCDs issued by different contractors.

Going through an NCD process is not necessarily bad from the perspective of the medical technology advocates, since 71% of procedures received a favorable national and local coverage decision. I expect this to be particularly true when the NCD process is initiated by a company or individual with an interest in a favorable coverage decision, since once they initiate the process they are usually well prepared to present the evidence in favor of reimbursement. However, future research is needed to find a possible correlation between the identity of the initiator of an NCD process and its outcome. This may be difficult, as gathering the information for such a research is not available, to the best of my knowledge, from the CMS website.

That the National Coverage Decision process is somehow not very structured is demonstrated by the fact that from 193 procedures that underwent coverage decisions, only 10 required a Technology Assessment and only 12 required a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). According to CMDs this is mainly because CMS has budget constraints and limits the use of TAs and MEDCACs to new technologies that require clear national coverage guidance, most of which are medical devices due to the lack of clinical effectiveness information in FDA device trials. None of the 12 procedures requiring an evaluation from the MEDCAC involved a specialty not represented in the MEDCAC, which could mean one of two things: that the MEDCAC composition is adequate or that there aren't procedures from these specialties evaluated by the MEDCAC precisely because they are not represented in it. From the 22 decisions involving TAs or MEDCACs, only 4 were not approved, which means that going through one of these more structured processes is not necessarily bad for reimbursement advocates. The reason for this might be that the basis for the evaluation is clearer and known in advance, resulting in better preparation to present the evidence from the parties interested in coverage. All other national decisions were taken at the discretion of CMS authorities, many without information disclosure of the criteria used to evaluate the clinical value of the procedure. On the other hand, most LCDs mention the basis of their decision, which usually are journals, CMS, external organizations or other carriers' decisions.

The states with a higher number of issued LCDs are mainly located in the East Coast and the Great Lakes areas. It is interesting to note that the majority of MEDCAC members are also concentrated in these two regions, although, to the best of my knowledge, they are not supposed to be involved with Local Coverage Determinations, so this would be a coincidental finding. Apart from the analyzed variables thought to be related to LCD issuing activity in the present study, these states might share common characteristics that could reveal other possible variables that explain a greater LCD issuing activity and in some cases more coverage discrepancies. As was explained in the Results section, on a preliminary analysis, I hypothesized that contractors may be one of these variables. However, I didn't find any indication of this. Future research is needed to find possible predictors of LCD issuing activity based on characteristics common to these states. One common characteristic shared by these states is that they are home to many of the most influential medical device, biotechnology and pharmaceutical companies. Some other possible drivers mentioned by CMDs of such LCD issuing activity that could have local variations and that merit further research, are:

- The necessity to automate legitimate denials
- A history of abuse and fraud

- CMD's experience, ambition and interests
- Human and economic resources available to the contractor to issue LCDs
- Contractor's philosophy towards coverage policies
- Perceived need for an LCD
- Level of sophistication of data analysis of utilization patterns, quality of care and billing errors

Kansas and New York are of particular interest due to their large number of discrepancies between LCDs and NCDs not explained by greater LCD issuing activity. Since most of these discrepancies are exclusions not mentioned in NCDs, some possible factors that merit further research are: a history of abuse and fraud, a greater perceived need for an LCD, the CMD profile and a greater data analysis capability in these states. On the other hand, Florida, the Virgin Islands, North Carolina and South Carolina have a greater rate of LCDs equal to NCDs. The same variables, pointing in the opposite direction, can be responsible for these differences. Further research is needed to find possible drivers of these coverage discrepancies and similarities.

On a national level, the present study shows that discrepancies between NCDs and LCDs coverage limitations are not explained by the hypothesized factors. However, some sub-analysis results showed some possible correlations when comparing the same variables between regions and between states from the same region. As I mentioned in the Results section above, the analysis between regions showed that as the number of Medical Schools increases and the ranking of Level 1 and 2 Trauma Centers (adjusted for population density) is better (lower ranking number), the total number of issued LCDs increases, including those that differ from NCDs as well as those that are the same. This is contrary to hypothesis, since having more issued LCDs is not supposed to be in favor of physician's and hospitals interests, if it is the case that this excess LCD activity limits reimbursement for them. However, it could be the case that this higher number of LCDs somehow favors physician's and hospital's interests for these procedures.

In the statistical analysis within each region I found some interesting correlations in the Central and West Coast regions, as mentioned in the Results section. In the Central US I found that that with a better ranking of Level 1 and 2 Trauma Centers (lower ranking number), more LCDs differed from NCDs and more LCDs were issued. These results were unexpected according to the initial hypothesis. Somehow hospital's interests in this region have generated a greater LCD activity. In the West Coast, I found that the number of Schools of Medicine and the number of physicians are

positively correlated with the number of LCDs that are different from NCDs and the total number of issued LCDs. Again, this is the contrary of what was initially expected: a lower policy discrepancy and a lower number of LCDs.

The correlations founded in the sub-analysis have to be taken with caution and merit further research, since the number of states in the samples is too small to arrive to a conclusion based on these data points.

Although few analyzed procedures have required MEDCACs, an analysis of its membership profile can be important if decisions are supposed to be more structured in the future with the Medicare Contracting Reform. The typical MEDCAC member is a 53 years old male MD with a specialty doing research on an academic Institution located in the East Coast or the Great Lakes area. Beyond this stereotype, the general composition of the MEDCAC is comprehensive with respect to the different points of view and areas of expertise required to evaluate the clinical value of medical procedures, including industry representatives, patient advocates and experts in health policy, health outcomes, epidemiology, biostatistics, pharmacology, nursing, occupational, preventive and family medicine, public policy, law, psychology, sociology and at least one representative of the most important medical specialties, with the previously mentioned important exceptions. Although a majority of members (59%) work in academic Institutions, there is an important representation from the medical industry, private health systems and health quality organizations. At the local level, on the other hand, CACs fulfill only an advisory role and are not as influential as MEDCACs. CACs are often composed of physicians who are not necessarily opinion leaders and very often the evidence required to convince a CAC of the clinical value of a procedure is lower than the evidence required to convince a MEDCAC.

VI. Conclusions and recommendations

The following conclusions and recommendations can be drawn from the previous analysis and discussion of results:

- The majority of procedures (64%) that have an NCD don't have any LCD at all. Further research is needed to determine the factors that characterize the procedures for which LCDs are issued having an NCD already in place. These could be any of the drivers of LCD issuing activity discussed in the previous section.
- There is a reasonable degree of homogeneity in coverage policies (82% are exactly the same) for procedures for which an NCD has been issued. The degree of homogeneity or variability between LCDs from different states is beyond the scope of this study and would be interesting to explore in the future.
- The majority of differences between NCDs and LCDs come in the form of conditions and diagnosis that are **not excluded** in the NCD, while being **excluded** in the LCD, restricting coverage to certain CPT and ICD-9 codes. CMS is clear that when an NCD mentions a covered condition or diagnosis, it doesn't mean they should be the only ones covered, it leaves that decision to the discretion of the contractors through the LCDs. Thus, although LCDs don't openly contradict NCDs (they never deny coverage for conditions specified in NCDs as covered, except for the Mitogen Response Assays already mentioned), they use the open space left by NCDs to restrict coverage according to their local demands. According to CMDs, the reason why CMS leaves many exclusion decisions open to contractor's discretion is because it doesn't have the resources and speed to manage all this policy activity and because CMS wants to let contractors adapt the NCDs to their local needs. A future interesting research topic could be to explore whether shifting this policy activity back to CMS, making exclusion decisions and assigning billing codes directly in NCDs, could decrease coverage policy variability, if this could be feasible from an operational and administrative perspective and even if homogeneity in coverage policies is desirable.
- The majority of the procedures (71%) that go through an NCD process receive a positive coverage decision. The degree of limitations on this positive coverage decision and its adequacy to standard medical

practice or clinical evidence is not assessed on this study and would be an interesting question to ask in future coverage research.

- If the majority of procedures (82%) for which an NCD has been issued have exactly the same coverage policies for all states and the majority of NCDs are positive (in 71% of cases the procedure is covered), it follows that, for the majority of procedures, reimbursement advocates - including hospitals, physicians, industry and consumers- should pursue NCDs instead of LCDs. On top of that, if LCDs are more restrictive than NCDs, then, reimbursement advocates shouldn't be in favor of LCD issuing activity. The only parties favored by LCD issuing activity are clearly Medicare and to some extent its contractors, who, by automating the denial of some claims, may decrease their operating costs.
- In the majority of cases, the NCD process is left to the discretion of CMS authorities, without any TA or MEDCAC involved in the decision process. Some possible explanations for this are CMS budget constraints or limiting the use of TAs or MEDCACs strictly to new technologies, the majority of which are medical devices.
- Although MEDCACs are composed mostly of academic MD specialists, the general composition of the MEDCAC is comprehensive with respect to the different points of view and areas of expertise required to evaluate the clinical value of medical procedures. On the other hand, at the local level, CACs are often composed of physicians who are not necessarily opinion leaders. In many cases, the evidence required to convince a CAC of the clinical value of a procedure is lower than the evidence required to convince a MEDCAC. That's one of the reasons why many medical device manufacturers and pharmaceutical companies prefer the local route to gain coverage for their products. Other reasons are that LCDs take less time than NCDs to complete and once a contractor accepts coverage of a procedure, it is easier to convince other contractors.
- From a public policy perspective, clearer rules on coverage decisions at the national level (meaning increased use of TAs or MEDCACs) would incentivize industry leaders to pursue the national route for coverage and this might attract more investment towards cost-effective medical innovations, as reimbursement risk decreases.

- The states with a higher degree of LCD issuing activity are located in the East Coast and the Great Lakes areas. These states might share common characteristics that account for this greater LCD issuing activity and that merit further research, including: the necessity to automate legitimate denials; a history of abuse and fraud; CMD's experience, ambition and interests; budget size for issuing LCDs; contractor's philosophy towards coverage policies; perceived need for an LCD and level of sophistication of data analysis of utilization patterns, quality of care and billing errors.
- Two states, Kansas and New York, have a higher rate of discrepancy not explained by an increase in LCD issuing activity, while four states, Florida, the Virgin Islands, North Carolina and South Carolina, have a lower rate of discrepancies not explained by a lower LCD issuing activity. Some possible drivers of this higher or lower rate of discrepancies that need to be studied in the future could be: history of abuse and fraud, perceived need for an LCD, the CMD profile and data analysis capability.
- On a national level, **discrepancies between NCDs and LCDs are not explained by the hypothesized factors:** number of Schools of Medicine, number of physicians, GDP per capita, State Ranking according to number of Level 1 and Level 2 Trauma Centers, population density per square mile and MEDCAC members characteristics.
- A sub-analysis between regions showed a significant positive correlation ($r^2 > 0.94$) between the number of issued LCDs and the number of Schools of Medicine and between the number of issued LCDs and the ranking of Level 1 and Level 2 Trauma Centers. Having a greater LCD issuing activity could favor physicians' and hospitals' interests.
- A sub-analysis between states of the same region showed that in the Central US, a better ranking according to Level 1 and 2 Trauma Centers is correlated ($r^2 > 0.95$) with a higher LCD issuing activity and a greater degree of differences between LCDs and NCDs. Having more sophisticated hospitals could be a driver of LCD issuing activity and greater differences between LCDs and NCDs. In the West Coast, the number of Schools of Medicine and the number of physicians are positively correlated ($r^2 > 0.99$) with the total number of LCDs and the number of LCDs that differ from NCDs, showing again that physician's

interests could be a driver of LCD issuing activity and of differences between LCDs and NCDs.

- The correlations shown by the performed sub-analysis within regions may imply that more LCDs are issued to restrict coverage when there is a local need to control the excessive demand partially driven by the higher number of hospitals and physicians that are active in pursuing their interests. The fact that these correlations were shown only at a regional level may indicate that when local factors are disregarded, the original hypothesized factors do influence LCD activity, however, at a national level, other hypothetical local factors may have a greater influence on LCD activity and policy discrepancies. The higher LCD issuing activity in the East Coast and Great Lakes areas confirm the geographical nature of these other hypothetical factors.
- Medicare Contracting Reform will cause more homogeneous policies between states but there will still be differences between states belonging to different contractors. After Contracting Reform, there will no longer be differences between Part A and Part B policies.

VII. Tables

Table 1. Inpatient Hospital Services

NCD				LCD						
NCD title	Covered (0=N, 1=Y)	TA (0=N, 1=Y)	MEDCAC (0=N, 1=Y)	Contractor	Contractor Type	States	Covered?	Limitations different to NCD? (0=different, 1=same)	Limitations different to other LCDs? (0=different, 1=same)	Base of Decision
Abarelix for the treatment of prostate cancer	1	0	0	First Coast Serv	MAC Part A and	Florida	1	1	1	CMS
				First Coast Serv	MAC Part A and	Puerto Rico, Vir	1	1	1	CMS
Acupuncture	0	0	0							
Acupuncture for fibromyalgia	0	1	0							
Acupuncture for Osteoarthritis	0	1	0							
Adult liver transplantation	1	0	0							
Anesthesia in Cardiac Pacemaker Surgery	1	0	0							
Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	0 or 1	0	0							
Bariatric Surgery for Treatment of Morbid Obesity	1	0	1	Wisconsin Phys	MAC Part A	lows, Kansas, M	1	1	1	CMS
				Palmetto GBA	MAC Part B	California North	1	1	1	CMS
				National Govern	FL/Carrier/MAC	Indiana, Illinois,	1	1	1	CMS
				CIGNA Governm	Carrier	North Carolina,	1	0	0	Journals
Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (Effective March 20, 2007)	0	0	0							
Blood Platelet Transfusions	1	0	0							
Blood Transfusions	1	0	0							
Cardiac Pacemakers	1	0	0							
Closed-Loop Blood Glucose Control Device (CBGCD)	1	0	0							
Cryosurgery of Prostate	1	0	0	First Coast Opt	MAC Part A	Florida, Puerto f	1	0	1	Journals
Dental Examination Prior to Kidney Transplantation	1	0	0							
Extracranial-Intracranial (EC-IC) Arterial Bypass Surgery	0	0	0							
Granulocyte Transfusions	1	0	0							
Heart Transplants	1	0	0							
Inpatient Hospital Pain Rehabilitation Programs	1	0	0							
Inpatient Hospital Stays for Treatment of Alcoholism	1	0	0							
Intestinal and Multi-Visceral Transplantation	1	0	0							
Intestinal Bypass Surgery	0	0	0							
Intraoperative ventricular mapping	1	0	0							
Invasive Intracranial Pressure Monitoring	1	0	0							
Islet Cell Transplantation in the Context of a Clinical Trial	1	0	0							
Laparoscopic Cholecystectomy	1	0	0							
L-Dopa	1	1	0							
Lumbar Artificial Disc Replacement (LADR)	0	0	0	Noridian Admini	Carrier, MAC Pa	Alaska, Oregon,	0	0	1	Technology Ass
Lung Volume Reduction Surgery (Reduction Pneumoplasty)	1	0	0	First Coast Serv	MAC Part A	Florida, Puerto f	1	1	1	CMS
Nesiritide for Treatment of Heart Failure Patients	0	0	0	First Coast Serv	MAC Part A, MA	Florida, Puerto f	1	0	0	Journals
				National Govern	FL, Carrier, MAC	Indiana, Illinois,	1	0	0	Journals
				Palmetto GBA	MAC Part A	California, Amer	1	0	0	Journals
Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation	1	0	0							
Pancreas Transplants	1	0	0							
Pediatric Liver Transplantation	1	0	0							
Percutaneous Image-Guided Breast Biopsy	1									
Percutaneous Transluminal Angioplasty (PTA)	1			Palmetto GBA	Carrier	Ohio, West Virgi	1	0	1	Journals
Postural Drainage Procedures and Pulmonary Exercises	1	0	0							
Stem Cell Transplantation	1	0	1	National Govern	FL, Carrier, MAC	Indiana, Illinois,	1	0	1	Journals
Stereotactic Craniotomy as a Means of Psychosurgery	0	0	0							
Thoracic Duct Drainage (TDD) in Renal Transplants	1	0	0							
Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain	1	0	0	CIGNA Governm	DME MAC	Alabama, Arkan	1	0	1	NA
				Noridian Admini	DME MAC	Alaska, America	1	0	1	NA
				NHIC Corp	DME MAC	Connecticut, Dis	1	0	1	NA
				National Govern	DME MAC	Illinois, Indiana,	1	0	1	NA
Transmyocardial Revascularization (TMR)	1	0	1	First Coast Serv	MAC Part B	Florida, Puerto f	1	1	1	Journals
Ultrafiltration, Hemoperfusion and Hemofiltration	1	0	0							
Ultrasound Diagnostic Procedures	1	0	0							
Vertebral Artery Surgery	1	1	0							

Table 2. Durable Medical Equipment

NCD title	NCD			LCD						
	Covered (0=N, 1=Y)	TA (0=N, 1=Y)	MEDCAC (0=N, 1=Y)	Contractor	Contractor Type	States	Covered?	Limitations different to NCD? (0=different, 1=same)	Limitations different to other LCDs? (0=different, 1=same)	Base of Decision
Continuous Positive airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)	1	0	1	Noridian Admini	DME MAC	Alaska, America	1	0	1	NA
				CIGNA Governm	DME MAC	Alabama, Arkan	1	0	1	NA
				NHIC Corp	DME MAC	Connecticut, Di	1	0	1	NA
				National Govern	DME MAC	Illinois, Indiana,	1	0	1	NA
Home Blood Glucose Monitors	1	0	1	Noridian Admini	DME MAC	Alaska, America	1	0	1	NA
				CIGNA Governm	DME MAC	Alabama, Arkan	1	0	1	NA
				NHIC Corp	DME MAC	Connecticut, Di	1	0	1	NA
				National Govern	DME MAC	Illinois, Indiana,	1	0	1	NA
Independence IBOT 4000 Mobility System	1	0	0							
Infrared Therapy Devices	0	0	0							
Infusion Pumps	1	0	0	NHIC Corp	DME MAC	Connecticut, Di	1	0	1	NA
				CIGNA Governm	DME MAC	Alabama, Arkan	1	0	1	NA
				Noridian Admini	DME MAC	Alaska, America	1	0	1	NA
				National Govern	DME MAC	Illinois, Indiana,	1	0	1	NA
Intrapulmonary Percussive Ventilator (IPV)	0	0	0	NHIC Corp	DME MAC	Connecticut, Di	0	NA	NA	NA
				CIGNA Governm	DME MAC	Alabama, Arkan	0	NA	NA	NA
				Noridian Admini	DME MAC	Alaska, America	0	NA	NA	NA
				National Govern	DME MAC	Illinois, Indiana,	0	NA	NA	NA
Mobility Assistive Equipment (MAE)	1	0	0							
Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases	No NCD is appr	0	0							
Noncontact Normothermic Wound Therapy (NNWT)	0	0	1	Wisconsin Phys	Carrier, MAC A,	Wisconsin, Illino	0	0	1	Journals
Non-implantable Pelvic Floor Electrical Stimulator	1	0	0	National Govern	Fl, Carrier, MAC	Indiana, Illinois,	1	1	1	Journals
				NHIC Corp	MAC A, MAC B	Maine, New Har	1	1	1	Journals
				Wisconsin Phys	Carrier, MAC B	Wisconsin, Illino	1	1	1	Journals
Osteogenic Stimulators	1	0	0	First Coast Serv	MAC B	Florida, Puerto F	1	1	1	NA
Pneumatic Compression Devices	1	0	0	CIGNA Governm	DME MAC	Alabama, Arkan	1	1	1	NA
				Noridian Admini	DME MAC	Alaska, America	1	1	1	NA
				NHIC Corp	DME MAC	Connecticut, Di	1	1	1	NA
				National Govern	DME MAC	Illinois, Indiana,	1	1	1	NA
Self-Contained Pacemaker Monitors	1	0	0							
Speech Generating Devices	1	0	0	Noridian Admini	DME MAC	Alaska, America	1	0	1	NA
				CIGNA Governm	DME MAC	Alabama, Arkan	1	0	1	NA
				NHIC Corp	DME MAC	Connecticut, Di	1	0	1	NA
Tinnitus Masking	0			National Govern	DME MAC	Illinois, Indiana,	1	0	1	NA
Vagus Nerve Stimulation (VNS)	1	0	0	TrailBlazer Healt	MAC Part A, MA	Colorado, New I	1	0	1	Journals

Table 3. Diagnostic Laboratory Tests

NCD title	NCD			LCD						
	Covered (0=N, 1=Y)	TA (0=N, 1=Y)	MEDCAC (0=N, 1=Y)	Contractor	Contractor Type	States	Covered?	Limitations different to NCD? (0=different, 1=same)	Limitations different to other LCDs? (0=different, 1=same)	Base of Decision
Alpha-fetoprotein	1	0	0							
Blood Counts	1	0	0							
Blood Glucose Testing	1	0	0	Palmetto GBA	FI	North Carolina	1	1	0	Burtis and Ashw
Carcinoembryonic antigen	1	0	0							
Collagen Crosslinks	1	0	0							
Diagnostic Pap Smears	1	0	0	Palmetto GBA	FI	South Carolina	1	1	1	Carr B, Bradsha
Digoxin Therapeutic Drug Assay	1	0	0							
Fecal Occult Blood Test	1	1	0	Palmetto GBA	FI	North Carolina, ;	1	0	0	Fauci AS, Braun
				Pinnacle Busine	Carrier, FI	Arkansas, Louis	1	0	0	American Socie
				National Govern	FI, Carrier, MAC	Indiana, Illinois,	1	1	0	CMS
				Palmetto GBA	MAC Part A	California, Amer	1	1	0	CMS
				First Coast Serv	MAC Part A, MA	Florida, Puerto F	1	0	0	Fauci, A., Braun
				NHIC Corp	MAC Part B	Maine, New Har	1	1	0	CMS
Gamma Glutamyl Transferase	1	0	0							
Glycated Hemoglobin/Glycated Protein	1	0	0							
Hepatitis Panel/Acute Hepatitis Panel	1	0	0							
Histocompatibility Testing	1	0	0							
Human Chorionic Gonadotropin	1	0	0							
Human Immunodeficiency Virus (HIV) Testing (Diagnosis)	1	0	0							
Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)	1	0	0							
Human Tumor Stem Cell Drug Sensitivity Assays	0	0	0	Palmetto GBA	Carrier	South Carolina,	0	1	1	Journals
Lipid Testing	1	0	0	National Govern	FI, Carrier, MAC	Indiana, Illinois,	1	0	1	Journals
Lymphocyte Mitogen Response Assays	1	0	0	National Govern	FI, MAC Part A,	Indiana, Illinois,	0	0	1	Journals
				Highmark Medic	MAC Part A, MA	Delaware, Distri	0	0	1	Bernstein I, Li J,
Partial Thromboplastin Time (PTT)	1	0	0	National Govern	FI, MAC Part A,	Indiana, Illinois,	1	0	1	Journals
Pharmacogenomic Testing for Warfarin Response	1	0	0							
Prostate Specific Antigen	1	0	0	Palmetto GBA	MAC Part B	California, Amer	1	0	0	Journals
				TrailBlazer Healt	MAC Part A, MA	Colorado, New I	1	0	0	TrailBlazer adop
				National Govern	FI	Indiana, Illinois,	1	0	0	Journals
Prothrombin Time (PT)	1	0	0	National Govern	FI, MAC Part A,	Indiana, Illinois,	1	0	1	Journals
Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS)	1	0	0							
Serum Iron Studies	1	0	0							
Thyroid Testing	1	0	0							
Tumor Antigen by Immunoassay - CA 125	1	0	0							
Tumor Antigen by Immunoassay - CA 15-3/CA 27.29	1	0	0							
Tumor Antigen by Immunoassay - CA 19-9	1	0	0							
Urine Culture, Bacterial	1	0	0							

Table 4. Physician's Services

NCD title	NCD				LCD						
	Covered (0=N, 1=Y)	Limitations	TA (0=N, 1=Y)	MEDCAC (0=N, 1=Y)	Contractor	Contractor Type	States	Covered?	Limitations different to NCD? (0=different, 1=same)	Limitations different to other LCDs? (0=different, 1=same)	Base of Decision
Abortion	0	Abortions are not covered	0	0							
Apheresis (Therapeutic Pheresis)	1	See policy	0	0	NHIC Corp	MAC Part B, MF	Maine, New Har	1	0	1	Journals
Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy	1	See policy	1	0							
Autogenous Epidural Blood Graft	1	Autogenous epidural blood graft	0	0							
Biofeedback Therapy	1	Biofeedback therapy	0	0	Wisconsin Phys Carrier		Wisconsin, Illinois	1	0	0	Journals
					First Coast Serv	MAC Part B, MF	Florida, Puerto F	1	1	0	Journals
					Cahaba Govern	MAC Part A	Alabama, Georg	1	0	0	Journals
					National Govern FI, Carrier		Indiana, Illinois,	1	0	0	Journals
					NHIC Corp	MAC Part B, MF	Maine, New Har	1	0	0	Journals
Breast Reconstruction Following Mastectomy	1	Reconstruction	0	0	Wisconsin Phys Carrier		Wisconsin, Illinois	1	1	1	Journals
Carotid Body Resection/Carotid Body Denervation	0	Carotid body resection/denervation	0	0							
Cellular Therapy	0	Cellular therapy	0	0							
Chelation Therapy for Treatment of Atherosclerosis	0	EDTA chelation	0	0	Trailblazer Health	MAC Part B, MF	Colorado, New I	0	1	1	CMS, TrailBlaze
Cochleostomy with Neurovascular Transplant for Meniere's Disease	0	While there are no contraindications	0	0							
Collagen Meniscus Implant	0	The Centers for Medicare and Medicaid Services has not approved this procedure	0	0							
Colonic Irrigation	0	There are no contraindications	0	0							
Deep Brain Stimulation for Essential Tremor and Parkinson's Disease	1	See policy	0	0							
Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS)	1	Dermal injection	0	0							
Diagnosis and Treatment of Impotence	1	Program payment	0	0	National Govern FI, Carrier		Indiana, Illinois,	1	0	1	Journals
Diagnostic Endocardial Electrical Stimulation (Pacing)	1	Diagnostic endocardial electrical stimulation	0	0							
Diathermy Treatment	1	High energy pulsed radio frequency	0	0	Palmetto GBA	FI, MAC Part A	North Carolina, South Carolina,	1	1	0	CMS
					National Govern FI, Carrier, MAC		Indiana, Illinois,	1	0	0	Journals
					NHIC Corp	MAC Part B, MF	Maine, New Har	1	0	0	Journals
					Highmark Medic	MAC Part B, MF	Delaware, District of Columbia,	1	0	0	Journals
					Pinnacle Busine FI, Carrier		Arkansas, Louis	1	0	0	Journals
					Cahaba GBA, LI RHHI		Colorado, District of Columbia,	1	0	0	Journals
Electrical Aversion Therapy for Treatment of Alcoholism	0	Electrical aversion	0	0	National Govern FI, Carrier, MAC		Indiana, Illinois,	0	1	1	CMS
					Palmetto GBA	MAC Part A, FI	California, Amer	0	1	1	CMS
					First Coast Serv	MAC Part A	Florida, Puerto F	0	1	1	CMS
					NHIC Corp	MAC Part B, MF	Maine, New Har	0	1	1	CMS
					Wisconsin Phys	MAC Part A, FI	Alaska, Alabama,	0	1	1	CMS
Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds	1	ES and electromagnetic therapy	0	1	Pinnacle Busine FI		Louisiana, Missi	1	0	0	Journals
					Cahaba GBA, LI	MAC Part A	Alabama, Georg	1	0	0	Journals
					National Govern FI, Carrier, MAC		Indiana, Illinois,	1	0	0	Journals
					NHIC Corp	MAC Part B, MF	Maine, New Har	1	0	0	Journals
					Cahaba GBA, LI RHHI		Colorado, District of Columbia,	1	0	0	Journals
					Wisconsin Phys Carrier, MAC A,		Wisconsin, Illino	1	1	0	CMS
					TrailBlazer Health	MAC Part B, MF	Colorado, New I	1	1	0	CMS
Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature	1	The EEG monitoring	0	0							
Electroencephalographic (EEG) Monitoring During Open-Heart Surgery	0	Medicare does not cover this procedure	0	0							
Electrosleep Therapy	0	Until scientific evidence is available	0	0	National Govern FI, Carrier, MAC		Indiana, Illinois,	0	1	1	CMS
					Palmetto GBA	MAC Part A, FI	California, Amer	0	1	1	CMS
					First Coast Serv	MAC Part A	Florida, Puerto F	0	1	1	CMS
					NHIC Corp	MAC Part B, MF	Maine, New Har	0	1	1	CMS
					Wisconsin Phys	MAC Part A, FI	Alaska, Alabama,	0	1	1	CMS
Electrotherapy for Treatment of Facial Nerve Paralysis (Bell's Palsy)	0	Electrotherapy for facial nerve paralysis	0	0							
Ethylene diamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis	0	The use of EDTA chelation	0	0							
External Counterpulsation (ECP) Therapy for Severe Angina	1	See policy	0	0	First Coast Serv	MAC Part A	Florida, Puerto F	1	1	0	CMS and Journals
					Pinnacle Busine Carrier, FI		Arkansas, Louis	1	1	0	CMS
					Palmetto GBA	MAC Part B	California, Amer	1	0	0	Journals
					TrailBlazer Health	MAC Part A, MF	Colorado, New I	1	1	0	TrailBlazer Health
					Cahaba GBA, LI	MAC Part A	Alabama, Georg	1	0	0	Journals
Extracorporeal Photopheresis	1	The CMS has determined that this procedure is not medically necessary	0	0							
Fabric Wrapping of Abdominal Aneurysms	0	Fabric wrapping	0	0							
Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders	1	Use of fluidized heat	0	0	Palmetto GBA	FI, MAC Part A	North Carolina, South Carolina,	1	1	1	CMS
					National Govern FI, Carrier, MAC		Indiana, Illinois,	1	1	1	CMS
					NHIC Corp	MAC Part B, MF	Maine, New Har	1	1	1	CMS
					First Coast Serv	MAC Part A, MF	Florida, Puerto F	1	1	1	CMS
Gastric Balloon for Treatment of Obesity	0	The use of the gastric balloon	0	0	Wisconsin Phys	MAC Part A	Iowa, Kansas, M	0	1	1	CMS
					Palmetto GBA	MAC Part B	California North	0	1	1	CMS
					National Govern FI/Carrier/MAC		Indiana, Illinois,	0	1	1	CMS
					TrailBlazer Health	MAC Part A, MF	Colorado, New I	0	1	1	CMS

NCD title	Covered (0=N, 1=Y)	Limitations	TA (0=N, 1=Y)	MEDCAC (0=N, 1=Y)	Contractor	Contractor Type	States	Covered?	Limitations different to NCD? (0=different, 1=same)	Limitations different to other LCDs? (0=different, 1=same)	Base of Decision
Gastric Freezing	0	Gastric freezing	0	0							
Gastrophotography	1	Gastrophotogra	0	0							
Heat Treatment, Including the Use of Diathermy and Ultra-Sound for Pulmonary Conditions	0	There is no phys	0	0	Cahaba GBA, LI	MAC Part A, RH	Alabama, Georg	0	1	1	CMS
					Palmetto GBA	FI, MAC Part A	North Carolina, :	0	1	1	CMS
					National Govern FI, Carrier, MAC	Indiana, Illinois,		0	1	1	CMS
					NHIC Corp	MAC Part B, Mf	Maine, New Har	0	1	1	CMS
					Wisconsin Phys Carrier, MAC Pa	Wisconsin, Illino		0	1	1	CMS
					Highmark Medic	MAC Part B, Mf	Delaware, Distri	0	1	1	CMS
					Pinnacle Busine FI, Carrier	Arkansas, Louis		0	1	1	CMS
					Palmetto GBA	RHHI	Alabama, Arkan	0	1	1	CMS
					First Coast Serv	MAC Part A, Mf	Florida, Puerto f	0	1	1	CMS
Hemodialysis for Treatment of Schizophrenia	0	Scientific evider	0	0	National Govern FI, Carrier, MAC	Indiana, Illinois,		0	1	1	CMS
					Palmetto GBA	MAC Part A, FI	California, Amer	0	1	1	CMS
					First Coast Serv	MAC Part A	Florida, Puerto f	0	1	1	CMS
					NHIC Corp	MAC Part B, Mf	Maine, New Har	0	1	1	CMS
					Wisconsin Phys	MAC Part A, FI	Alaska, Alabam	0	1	1	CMS
Hyperbaric Oxygen Therapy	1	See policy	1	0	First Coast Serv	MAC Part A, Mf	Florida, Puerto f	1	0	0	Journals
					Palmetto GBA	FI	North Carolina, :	1	0	0	Journals
					National Govern FI, Carrier, MAC	Indiana, Illinois,		1	0	0	Journals
Hyperthermia for Treatment of Cancer	1	Local hyperther	0	0							
Implantation of Anti-Gastroesophageal Reflux Device	1	The implantator	0	0							
Induced Lesions of Nerve Tracts	1	Surgically induc	0	0	Noridian Admini	Carrier, MAC Pa	Alaska, Oregon,	1	1	1	Journals
					Palmetto GBA	MAC Part B	California, Amer	1	1	1	Journals
Injection Sclerotherapy for Esophageal Variceal Bleeding	1	No limitations	0	0							
Intraocular Photography	1	Intraocular phot	0	0							
Intravenous Histamine Therapy	0	There is no scie	0	0							
Laser Procedures	1	Medicare recogn	0	0							
Magnetic Resonance Angiography	1	See policy	0	0	Palmetto GBA	FI	North Carolina, :	1	1	0	CMS
					CIGNA Governn	Carrier	North Carolina, I	1	1	0	CMS
					Pinnacle Busine	Carrier	Arkansas, Louis	1	0	0	
					National Govern FI, Carrier, MAC	Indiana, Illinois,		1	0	0	Journals
					First Coast Serv	MAC Part A, Mf	Florida, Puerto f	1	1	0	CMS
					Wisconsin Phys	MAC Part B	Iowa, Kansas, M	1	0	0	Other LCDs
					NHIC, Corp	MAC Part B	Maine, New Har	1	0	0	
					National Govern FI, Carrier, MAC	Indiana, Illinois,		0	1	1	CMS
Magnetic Resonance Spectroscopy	0	CMS has determ	1	0							
Manipulation	1	See policy									
Multiple Electroconvulsive Therapy (MECT)	0	The clinical effe	0	0	National Govern FI, Carrier, MAC	Indiana, Illinois,		0	1	1	CMS
					Palmetto GBA	MAC Part A, FI	California, Amer	0	1	1	CMS
					First Coast Serv	MAC Part A	Florida, Puerto f	0	1	1	CMS
					NHIC Corp	MAC Part B, Mf	Maine, New Har	0	1	1	CMS
					Wisconsin Phys	MAC Part A, FI	Alaska, Alabam	0	1	1	CMS
Ocular Photodynamic Therapy (OPT)	1	See policy	0	1	First Coast Serv	MAC Part A, Mf	Florida, Puerto f	1	1	0	Journals
					TrailBlazer Healt	MAC Part A, Mf	Colorado, New I	1	0	0	
Outpatient Intravenous Insulin Treatment	0	See policy	0	0							
Oxygen Treatment of Inner Ear/Carbon Therapy	0	Oxygen (95 perc	0	0							
Partial Ventriculectomy	0	Since the morta	0	0							
Phaco-Emulsification Procedure - Cataract Extraction	1	In view of recurr	0	0							
Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents	0	The medical effe	0	0	Palmetto GBA	MAC Part B	California, Amer	0	1	1	CMS
					Wisconsin Phys	MAC Part A, Mf	Alaska, Alabam	0	1	1	CMS
Smoking and Tobacco-Use Cessation Counseling	1	See policy									
Sterilization	1	Payment may be	0	0							
Surgery for Diabetes	1	Open and lapar	0	0							
Therapeutic Embolization	1	Therapeutic eml	0	0							
Thermal Intradiscal Procedures (TIPs)	0	The Centers for	0	0							
Thermogenic Therapy	0	Regardless of th	0	0							
Transcendental Meditation	0	After review of tl	0	0							
Transsexual Surgery	0	Transsexual sur	0	0							
Transvenous (Catheter) Pulmonary Embolectomy	0	It is not covered	0	0							
Treatment of Actinic Keratosis	1	No limitations	0	0	Highmark Medic	MAC Part A, Mf	Delaware, Distri	1	1	0	CMS
					Noridian Admini	MAC Part B	Arizona, Montar	1	0	0	Other LCDs
Treatment of Decubitus Ulcers	1	Hydrotherapy (w	0	0							

Table 5. Diagnostic Tests

NCD title	NCD			LCD							
	Covered (0=N, 1=Y)	TA (0=N, 1=Y)	MEDCAC (0=N, 1=Y)	Contractor	Contractor Type	States	Covered?	Limitations different to NCD? (0=different, 1=same)	Limitations different to other LCDs? (0=different, 1=same)	Base of Decision	
Ambulatory Blood Pressure Monitoring	1	1	1								
Ambulatory EEG Monitoring	1	0	0	0	Pinnacle Busine	Carrier, FI	Arkansas, Louis	1	0	1	Journals
					Wisconsin Phys	MAC Part B	Iowa, Kansas, M	1	0	1	Journals
					NHIC Corp	MAC Part A, MA	Maine, New Har	1	0	1	Journals
Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB)	1	0	0	0	National Govern	FI, Carrier, MAC	Indiana, Illinois,	1	0	0	Journals
					Palmetto GBA	MAC Part A	California, Amer	1	0	0	Journals
					CIGNA Govern	Carrier	North Carolina	1	0	0	Journals
					TrailBlazer Health	MAC Part A, MA	Colorado, New	1	1	0	
					First Coast Serv	MAC Part A, MA	Florida, Puerto	1	0	0	Journals
Cardiac Pacemaker Evaluation Services	1	0	0								
Cardiogram (CIG) as an Alternative to Stress Test or Thallium Stress Test	0	0	0								
Cavernous Nerves by Electrical Stimulation with Penile Plethysmography	0	0	0								
Challenge Ingestion Food Testing	1	0	0	0	Wisconsin Phys	MAC Part A, MA	Alaska, Alabama	1	0	1	Journals
Computed Tomography	1	1	0	0	National Govern	FI, Carrier, MAC	Indiana, Illinois,	1	0	1	Journals
Computer Enhanced Perimetry	1	0	0								
Cytogenetic Studies	1	0	0	0	CIGNA Govern	Carrier	North Carolina	1	0	0	Journals, CMS
					Nordian Admini	MAC Part B, Ca	Alaska, Oregon,	1	0	0	Journals
					Palmetto GBA	MAC Part B	California, Amer	1	0	0	Journals
					Wisconsin Phys	MAC Part A, MA	Alaska, Alabama	1	0	0	Journals
Cytotoxic Food Tests	0	0	0	0	Wisconsin Phys	FI	Alaska, Alabama	0	1	1	Journals
Diagnostic Breath Analyses	1	0	0								
Digital Subtraction Angiography	1	0	0								
Displacement Cardiography	1	0	0								
Electrocardiographic Services	1	0	0	0	Palmetto GBA	FI	North Carolina,	1	1	1	CMS
Electron Microscope	1	0	0								
Electroencephalographic (EEG) Monitoring During Open-Heart Surgery	0	0	0								
Endothelial Cell Photography	1	0	0								
Esophageal Manometry	1	0	0								
Evoked Response Tests	1	0	0								
Food Allergy Testing and Treatment	0	0	0	0	First Coast Serv	MAC Part B	Florida, Puerto	0	1	1	CMS
Gravitee Jet Washer	1	0	0								
Hair Analysis	0	0	0	0	CIGNA Govern	Carrier	Idaho, North Ca	0	1	1	Journals, CMS
Heartsbreath Test for Heart Transplant Rejection	0	0	0								
Hemorheograph	1	0	0								
HIS Bundle Study	1	0	0								
Mammograms	1	0	0	0	Wisconsin Phys	Carrier	Wisconsin, Illino	1	0	0	
					National Govern	FI, Carrier, MAC	Indiana, Illinois,	1	0	0	Journals
					NHIC, Corp.	MAC Part B, MA	Maine, New Har	1	0	0	Journals
					Palmetto GBA	FI	South Carolina,	1	0	0	Journals, CMS
					TrailBlazer Health	Carrier, MAC Pa	Virginia, Colorad	1	0	0	
					First Coast Serv	MAC Part B, MA	Florida, Puerto	1	0	0	
Microvolt T-Wave Alternans (MTWA)	1	0	0								
Noninvasive Tests of Carotid Function	1	0	0	0	Highmark Medic	MAC Part A, MA	Delaware, Distri	1	0	0	
					Palmetto GBA	MAC Part B, Ca	California, Amer	1	0	0	Journals
					Pinnacle Busine	Carrier	Arkansas, Louis	1	0	0	Journals
					National Govern	FI, Carrier, MAC	Indiana, Illinois,	1	0	0	Journals
					Wisconsin Phys	Carrier, MAC Pa	Alaska, Alabama	1	0	0	Journals
Nuclear Radiology Procedure	1	0	0								
PET for Perfusion of the Heart	1	0	0	0	Palmetto GBA	Carrier	Ohio, West Virg	1	0	0	Journals
					National Govern	FI, Carrier, MAC	Indiana, Illinois,	1	0	0	Journals
					NHIC, Corp.	MAC Part B, MA	Maine, New Har	1	0	0	Journals
					First Coast Serv	MAC Part A, MA	Florida, Puerto	1	1	0	CMS
					TrailBlazer Health	Carrier, MAC Pa	Virginia, Colorad	1	1	0	CMS
Plethysmography	1	0	0								
Positron Emission Tomography (FDG) for Oncologic Conditions	1	0	1	1	TrailBlazer Health	Carrier, MAC Pa	Virginia, Colorad	1	1	1	CMS
Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer	0	0	0								
Positron Emission Tomography (PET) Scans	Under review	0	1	1	First Coast Serv	MAC Part A, MA	Puerto Rico, Vir	1	0	1	NA
Single Photon Emission Computed Tomography (SPECT)	1	0	0	0	NHIC, Corp	MAC Part B, MA	Maine, New Har	1	0	1	Other LCDs
Stereotaxic Depth Electrode Implantation	1	0	0								
Sweet Test	1	0	0								
Thermography	0	0	0	0	Pinnacle Busine	FI, Carrier	Arkansas, Louis	0	1	1	Journals
					Highmark Medic	MAC Part A, MA	Delaware, Distri	0	1	1	
					Palmetto GBA	MAC Part B, Ca	California, Amer	0	1	1	Journals
					First Coast Serv	MAC Part A	Florida, Puerto	0	1	1	Journals
					National Govern	FI, Carrier, MAC	Indiana, Illinois,	0	1	1	Journals
					CIGNA Govern	Carrier	North Carolina	0	1	1	Journals
Transillumination Light Scanning or Diaphanography	0	0	0								
Uroflowmetric Evaluations	1	0	0								
Vabra Aspirator	0	0	0								
Xenon Scan	1	0	0								

Table 6. NCD and LCD Statistics by State

State	Inpatient Hospital Services			Durable Medical Devices			Diagnostic Laboratory			Physician's Services			Diagnostic Tests			Total		
	Limitations different to NCD? (0=different, 1=same)			Limitations different to NCD? (0=different, 1=same)			Limitations different to NCD? (0=different, 1=same)			Limitations different to NCD? (0=different, 1=same)			Limitations different to NCD? (0=different, 1=same)			Limitations different to NCD? (0=different, 1=same)		
	Number of 0	Number of 1	Total	Number of 0	Number of 1	Total	Number of 0	Number of 1	Total	Number of 0	Number of 1	Total	Number of 0	Number of 1	Total	Number of 0	Number of 1	Total
Alaska	2	0	2	5	1	6	0	0	0	7	8	15	2	1	3	12	9	21
Alabama	1	0	1	5	1	6	0	0	0	3	8	11	3	1	4	12	10	22
American Samoa	2	1	3	4	1	5	1	2	3	2	11	13	3	1	4	12	16	28
Arkansas	1	0	1	5	1	6	0	0	0	2	9	11	5	2	7	14	12	26
Arizona	2	0	2	5	1	6	0	0	0	1	7	8	4	1	5	12	9	21
California	2	1	3	4	1	5	1	2	3	2	11	13	3	1	4	12	16	28
Colorado	1	0	1	6	1	7	0	0	0	3	11	14	4	4	8	15	16	31
Connecticut	3	1	4	5	2	7	0	5	5	6	14	20	8	2	10	27	21	48
District of Columbia	1	0	1	5	1	6	1	1	2	2	8	10	4	2	6	13	11	24
Delaware	1	0	1	5	1	6	0	0	0	3	9	12	4	2	6	14	12	26
Florida	3	3	6	5	2	7	0	1	1	1	17	18	6	4	10	16	26	42
Georgia	1	0	1	5	1	6	0	0	0	3	8	11	3	1	4	12	10	22
Hawaii	2	1	3	4	1	5	1	2	3	4	9	13	3	1	4	14	14	28
Idaho	1	1	2	5	2	7	0	0	0	4	9	13	3	1	4	14	13	27
Illinois	2	0	2	5	1	6	0	0	0	0	7	7	3	2	5	10	10	20
Indiana	3	1	4	5	3	8	5	1	6	7	17	24	9	2	11	29	24	53
Iowa	1	0	1	5	2	7	0	0	0	6	15	21	8	2	10	27	21	48
Kansas	2	1	3	9	3	12	1	1	2	9	10	19	6	2	8	27	16	43
Kentucky	6	2	8	5	2	7	0	5	5	6	15	21	8	2	10	30	22	52
Louisiana	1	0	1	4	1	5	0	1	1	3	8	11	5	2	7	14	11	25
Massachusetts	1	0	1	5	2	7	0	1	1	4	12	16	7	1	8	17	16	33
Maryland	1	0	1	5	1	6	0	1	1	5	12	17	7	1	8	16	10	26
Maine	1	0	1	5	2	7	0	0	0	1	5	6	1	1	2	8	16	24
Michigan	3	1	4	5	3	8	5	1	6	7	16	23	9	2	11	29	23	52
Minnesota	1	0	1	5	2	7	0	0	0	2	7	9	4	1	5	12	10	22
Missouri	1	1	2	5	2	7	0	0	0	4	9	13	4	1	5	14	13	27
Mississippi	1	0	1	5	1	6	0	0	0	2	7	9	4	2	6	12	10	22
Montana	2	0	2	5	1	6	0	0	0	3	8	11	4	1	5	14	10	24
North Carolina	2	0	2	5	1	6	1	2	3	1	16	17	6	4	10	15	25	50
North Dakota	2	0	2	5	1	6	0	0	0	3	8	11	4	1	5	14	10	24
Ohio	1	1	2	5	2	7	0	0	0	4	9	13	4	1	5	14	13	27
Oklahoma	2	1	3	4	1	5	0	2	2	3	11	14	3	1	4	13	16	30
New Hampshire	1	0	1	5	2	7	0	1	1	5	12	17	7	1	8	18	16	34
New Jersey	1	0	1	5	1	6	1	1	2	1	8	9	4	2	6	12	11	23
New Mexico	1	0	1	6	1	7	0	1	1	1	11	12	4	4	8	13	16	30
New York	3	1	4	4	2	6	5	1	6	6	8	14	5	1	6	23	13	36
Northwest Territories																		
Islands	2	1	3	4	1	5	1	2	3	2	11	13	3	1	4	12	16	28
Ohio	4	1	5	5	2	7	0	5	5	6	15	21	10	2	12	30	22	52
Oklahoma	1	0	1	6	1	7	0	0	0	1	11	12	4	4	8	13	16	30
Oregon	2	0	2	5	1	6	0	0	0	3	7	8	4	1	5	12	9	21
Pennsylvania	1	0	1	5	1	6	0	0	0	3	9	12	4	2	6	14	12	26
Puerto Rico	3	3	6	4	2	6	1	0	1	3	10	11	3	1	4	12	18	30
Rhode Island	1	0	1	5	2	7	0	1	1	5	12	17	7	1	8	18	16	34
South Carolina	2	0	2	5	1	6	1	2	3	1	15	16	6	3	9	15	21	36
South Dakota	2	0	2	5	1	6	0	0	0	3	8	11	4	1	5	14	10	24
Tennessee	1	0	1	5	1	6	0	0	0	3	8	11	3	1	4	12	10	22
Texas	1	0	1	6	1	7	0	1	1	1	10	11	4	4	8	13	15	28
Utah	2	0	2	5	1	6	0	0	0	3	8	11	4	1	5	14	10	24
Virginia	4	1	5	6	2	8	5	1	6	7	17	24	11	6	17	33	27	60
Virgin Islands	1	0	1	6	2	8	1	0	1	1	16	17	6	4	10	14	22	42
Vermont	1	0	1	5	2	7	0	1	1	4	12	16	7	1	8	17	16	34
Washington	2	0	2	5	1	6	0	0	0	2	7	8	4	1	5	12	9	21
West Virginia	3	1	4	5	3	8	5	1	6	7	16	23	9	2	11	29	23	52
Wisconsin	4	1	5	5	2	7	0	5	5	6	15	21	10	3	13	32	22	54
Wyoming	2	0	2	5	1	6	0	0	0	3	8	11	4	1	5	14	10	24
USA	161	32	193	280	83	420	73	32	104	189	595	794	287	106	393	932	848	1680

Table 7. State Statistics

State	Number of Schools of Medicine (AAMC)	Number of physicians (1)	GDP per capita (2)	Level 1 and Level 2 Trauma Centers	Population Density per sq mile	Result	Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)
Alaska	0	270	43640	1	1.2	2.2	56
Alabama	2	2880	29411	2	91.87	93.87	34
American Samoa	0	50	8000	0	872	872	5
Arkansas	1	2920	27753	0	54.84	54.84	43
Arizona	1	4160	32343	1	57.2	58.2	41
California	8	21830	42064	41	235.68	276.68	18
Colorado	1	3100	41102	11	47.62	58.62	40
Connecticut	2	2500	50758	13	722.65	735.65	9
District of Columbia	3	1310	126407	3	9639	9642	1
Delaware	0	1220	56401	1	446.82	447.82	13
Florida	6	18930	32925	17	339.87	356.87	14
Georgia	4	3890	34017	9	167.27	176.27	24
Guam	0	50	19000	0	839.74	839.74	6
Hawaii	1	820	38644	1	200.56	201.56	20
Iowa	1	1530	36773	12	53.74	65.74	39
Idaho	0	920	29890	1	18.42	19.42	50
Illinois	7	12830	40006	61	232.11	293.11	17
Indiana	1	4440	32917	3	177.79	180.79	23
Kansas	1	1600	35013	3	34.25	37.25	47
Kentucky	2	2370	29740	2	107.46	109.46	29
Louisiana	3	3630	32842	2	101.25	103.25	33
Massachusetts	4	8950	48088	5	828.82	833.82	7
Maryland	3	9020	39205	7	576.39	583.39	10
Maine	0	1450	30637	3	42.66	45.66	45
Michigan	4	11030	32601	12	176.1	188.1	22
Minnesota	2	5060	41573	6	65.57	71.57	36
Missouri	4	4160	32779	19	85.82	104.82	32
Mississippi	0	550	24403	6	62.65	68.65	37
Montana	0	890	28170	3	6.65	9.65	54
North Carolina	4	6090	35719	9	189.33	198.33	21
North Dakota	1	490	37832	5	9.3	14.3	52
Nebraska	2	1560	37326	3	23.2	26.2	48
Nevada	1	1010	39687	2	23.68	25.68	49
New Hampshire	1	1540	38420	5	146.72	151.72	27
New Jersey	2	9980	44957	10	1170.64	1180.64	2
New Mexico	1	740	30935	1	16.35	17.35	51
New York	13	41030	49499	45	412.81	457.81	12
Northern Mariana Islands	0	38	12500	0	485.62	485.62	11
Ohio	6	12690	33568	20	280.5	300.5	16
Oklahoma	1	2640	29359	3	53.04	56.04	42
Oregon	1	4250	38801	7	39.48	46.48	44
Pennsylvania	7	11060	35641	25	277.76	302.76	15
Puerto Rico	4	980	17100	1	1162.07	1163.07	3
Rhode Island	1	1560	36283	1	1005.54	1006.54	4
South Carolina	2	2520	28364	6	148.79	154.79	26
South Dakota	1	220	37690	2	10.6	12.6	53
Tennessee	4	4960	33825	9	150.78	159.78	25
Texas	8	17820	38044	21	92.92	113.92	28
Utah	1	1520	32049	4	33.31	37.31	46
Virginia	4	7490	41769	7	196.22	203.22	19
Virgin Islands	0	40	22998	0	821.03	821.03	8
Vermont	1	630	34924	1	67.16	68.16	38
Washington	1	4530	40407	11	98.42	109.42	30
Wisconsin	2	5970	35239	5	103.63	108.63	31
West Virginia	2	1380	25533	4	75.36	79.36	35
Wyoming	0	210	40837	2	5.49	7.49	55

- 1) Doesn't include self employed doctors. Based on United States Department of Labor, Occupational Employment Statistics, May 2009
- 2) US Department of Commerce. Bureau of Economic Analysis, 2008

Table 8. Regressions All States

State	Number of Schools of Medicine (AAMC)	Number of times LCD-NCD	Number of Schools of Medicine (AAMC)	Number of times LCD different from NCD	Number of Schools of Medicine (AAMC)	Total number of times LCDs were issued	Number of physicians (1)	Number of times LCD-NCD	Number of physicians (1)	Number of times LCD different from NCD	Number of physicians (1)	Total number of times LCDs were issued
Alaska	0	12	0	9	0	22	276	12	270	9	270	22
Alabama	2	12	2	10	2	23	2880	12	2880	10	2880	23
American Samoa	0	12	0	16	0	29	50	12	50	16	50	29
Arkansas	1	14	1	12	1	27	3205	14	3205	12	3205	27
Arizona	1	12	1	9	1	22	4160	12	4160	9	4160	22
California	8	12	8	16	8	29	21830	12	21830	16	21830	29
Colorado	1	15	1	16	1	32	3100	15	3100	16	3100	32
Connecticut	2	27	2	21	2	46	3500	27	3500	21	3500	46
District of Columbia	3	10	3	11	3	25	1010	10	1010	11	1010	25
Delaware	0	14	0	12	0	27	1220	14	1220	12	1220	27
Florida	6	16	6	26	6	43	18930	16	18930	26	18930	43
Georgia	4	12	4	10	4	23	3890	12	3890	10	3890	23
Guam	0	14	0	14	0	29	50	14	50	14	50	29
Hawaii	1	14	1	14	1	29	820	14	820	14	820	29
Iowa	1	14	1	10	1	26	1530	14	1530	10	1530	26
Idaho	0	10	0	16	0	21	920	10	920	16	920	21
Illinois	7	20	7	24	7	54	12630	20	12630	24	12630	54
Indiana	1	27	1	21	1	49	4440	27	4440	21	4440	49
Kansas	1	27	1	16	1	45	1600	27	1600	16	1600	45
Kentucky	2	30	2	22	2	53	2370	30	2370	22	2370	53
Louisiana	3	14	3	11	3	26	3630	14	3630	11	3630	26
Massachusetts	4	17	4	16	4	34	8950	17	8950	16	8950	34
Maryland	3	16	3	10	3	27	9020	16	9020	10	9020	27
Maine	0	18	0	16	0	35	1450	18	1450	16	1450	35
Michigan	4	20	4	23	4	53	11030	20	11030	23	11030	53
Minnesota	2	12	2	10	2	23	5090	12	5090	10	5090	23
Missouri	4	14	4	13	4	28	4160	14	4160	13	4160	28
Mississippi	0	12	0	18	0	29	550	12	550	18	550	29
Montana	0	14	0	10	0	25	890	14	890	10	890	25
North Carolina	4	16	4	23	4	39	6000	16	6000	23	6000	39
North Dakota	1	14	1	18	1	26	490	14	490	18	490	26
Nebraska	2	14	2	13	2	28	1560	14	1560	13	1560	28
Nevada	1	13	1	16	1	30	1010	13	1010	16	1010	30
New Hampshire	1	18	1	16	1	35	1540	18	1540	16	1540	35
New Jersey	2	12	2	11	2	24	9980	12	9980	11	9980	24
New Mexico	1	13	1	16	1	30	740	13	740	16	740	30
New York	13	23	13	13	13	37	41030	23	41030	13	41030	37
Northern Mariana Islands	0	12	0	16	0	29	38	12	38	16	38	29
Ohio	6	36	6	22	6	53	12680	36	12680	22	12680	53
Oklahoma	1	13	1	16	1	30	2640	13	2640	16	2640	30
Oregon	1	12	1	9	1	22	4250	12	4250	9	4250	22
Pennsylvania	2	14	2	12	2	27	11060	14	11060	12	11060	27
Puerto Rico	4	12	4	18	4	31	980	12	980	18	980	31
Rhode Island	1	18	1	16	1	35	1560	18	1560	16	1560	35
South Carolina	2	16	2	21	2	37	2520	16	2520	21	2520	37
South Dakota	1	14	1	10	1	25	220	14	220	10	220	25
Tennessee	4	12	4	10	4	23	4960	12	4960	10	4960	23
Texas	8	13	8	15	8	29	17820	13	17820	15	17820	29
Utah	1	14	1	10	1	25	1520	14	1520	10	1520	25
Virginia	4	33	4	27	4	61	7480	33	7480	27	7480	61
Virgin Islands	0	14	0	27	0	42	40	14	40	27	40	42
Vermont	1	17	1	16	1	34	630	17	630	16	630	34
Washington	1	12	1	9	1	22	4530	12	4530	9	4530	22
Wisconsin	2	26	2	23	2	53	8970	26	8970	23	8970	53
West Virginia	2	32	2	22	2	55	1980	32	1980	22	1980	55
Wyoming	0	14	0	10	0	25	210	14	210	10	210	25
AVERAGE	2	17	2	15	2	33	4,916	17	4,916	15	4,916	33

1) Doesn't include self-employed doctors. Based on United States Department of Labor, Occupational Employment Statistics, May 2009
 2) US Department of Commerce, Bureau of Economic Analysis, 2008

Exponential	Linear	Pearson product-moment correlation coefficient
slope: 1.02285473 r2: 0.018480392 F: 3.85730270 Regression ss: 0.381517671	intercept: 14.59637125 slope: 0.017074992 r2: 0.052353322 F: 2.883383412 Regression ss: 0.317193298	0.252032301
intercept: 13.36726639 slope: 0.096098502 r2: 0.052353322 F: 2.883383412 Regression ss: 0.317193298	intercept: 10.36726639 slope: 0.017074992 r2: 0.052353322 F: 2.883383412 Regression ss: 0.317193298	0.229813796
intercept: 29.18578535 slope: 0.014823561 r2: 0.072645081 F: 4.242554302 Regression ss: 0.344742861	intercept: 30.29615975 slope: 0.540682719 r2: 0.067667955 F: 2.842091937 Regression ss: 418.9079975	0.280014028
intercept: 14.81580669 slope: 6.08647E-06 r2: 0.056266995 F: 3.340728113 Regression ss: 0.332926335	intercept: 15.6581002 slope: 0.00207573 r2: 0.00218207 F: 0.054442877 Regression ss: 116.0177705	0.329136042
intercept: 13.77132916 slope: 6.3607E-06 r2: 0.029611797 F: 1.61348601 Regression ss: 0.175767184	intercept: 14.5141399 slope: 9.96639E-06 r2: 0.029459325 F: 1.626050053 Regression ss: 44.03748309	0.17157216
intercept: 29.01287364 slope: 5.54833E-06 r2: 0.052693262 F: 3.07962005 Regression ss: 0.255063173	intercept: 31.17389334 slope: 0.00201128 r2: 0.048899218 F: 2.775317555 Regression ss: 302.4032453	0.22117872

State	GDP per capita (\$)	Number of times LCD=NCD
Alaska	6360	12
Alabama	29411	12
American Samoa	8000	12
Arizona	27753	12
Arkansas	35243	12
California	42064	12
Colorado	41102	10
Connecticut	60796	27
District of Columbia	126407	13
Delaware	56401	12
Florida	32965	28
Georgia	34017	12
Hawaii	19000	14
Idaho	38644	14
Illinois	36773	14
Indiana	29890	10
Iowa	40006	29
Kansas	32917	27
Kentucky	35613	27
Louisiana	29740	30
Maine	32942	11
Massachusetts	48088	17
Maryland	50206	16
Massachusetts	50637	18
Michigan	32891	23
Minnesota	41871	10
Missouri	32778	13
Mississippi	24403	10
Montana	28170	10
North Carolina	37742	25
North Dakota	37625	10
Ohio	37206	28
Oklahoma	30621	14
New Hampshire	38420	15
New Jersey	44807	13
New Mexico	30205	15
New York	49499	23
Northern Mariana Islands	12900	12
Ohio	33568	22
Oklahoma	29558	16
Oregon	38801	9
Pennsylvania	35641	27
Rhode Island	37100	10
Rhode Island	36263	15
South Carolina	38364	21
South Dakota	37690	15
Tennessee	33835	15
Texas	38044	15
Utah	32049	20
Virginia	41768	27
Virgin Islands	22998	14
Washington	34924	17
Washington	44092	5
Wisconsin	35209	23
West Virginia	25633	22
Wyoming	40837	14
AVERAGE	36.186	17

GDP per capita (\$)	Number of times LCD different from NCD
4306	8
29411	10
8000	16
27753	12
35243	8
42064	16
41102	10
60796	21
126407	13
56401	12
32965	28
34017	10
19000	14
38644	14
36773	13
29890	10
40006	24
32917	21
35613	16
29740	22
32942	11
48088	16
50206	10
50637	16
32891	23
41871	10
32778	13
24403	10
28170	10
37742	25
37625	10
37206	28
30621	14
38420	15
44807	13
30205	15
49499	11
12900	16
33568	22
29558	16
38801	9
35641	27
37100	10
36263	15
38364	21
37690	15
33835	15
38044	15
32049	20
41768	27
22998	14
34924	17
44092	5
35209	23
25633	22
40837	14
36.186	15

GDP per capita (\$)	Total number of times LCDs were issued
6360	22
29411	23
8000	28
27753	27
35243	22
42064	29
41102	32
60796	48
126407	20
56401	13
32965	14
34017	23
19000	29
38644	28
36773	31
29890	28
40006	54
32917	48
35613	45
29740	53
32942	28
48088	34
50206	27
50637	30
32891	63
41871	28
32778	30
24403	23
28170	25
37742	31
37625	20
37206	35
30621	31
38420	35
44807	34
30205	30
49499	37
12900	29
33568	63
29558	30
38801	22
35641	27
37100	31
36263	30
38364	26
37690	26
33835	23
38044	29
32049	25
41768	31
22998	42
34924	34
44092	22
35209	63
25633	35
40837	35
36.186	33

Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Number of times LCD=NCD
55	12
24	12
5	16
43	12
41	12
18	12
40	10
9	27
1	13
13	14
14	14
24	12
6	14
20	14
30	14
50	10
17	29
23	27
47	27
29	30
48	23
33	14
7	10
10	10
45	16
22	23
36	12
30	14
52	13
54	10
21	15
82	10
48	13
49	13
27	16
2	13
51	13
12	23
14	17

Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Number of times LCD different from NCD
56	9
24	10
5	16
43	12
41	12
18	12
40	16
9	27
1	11
13	12
14	14
24	10
6	14
20	14
30	13
50	10
17	24
23	21
47	16
29	22
48	23
33	11
7	10
10	10
45	16
22	23
36	10
30	14
52	13
54	10
21	15
82	10
48	13
49	16
27	16
2	11
51	13
12	13
11	16
16	22
42	18
44	9
15	12
3	18
4	16
26	21
53	10
28	10
29	10
46	10
19	21
8	27
38	16
30	9
31	23
35	22
58	10
29	15

Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Total number of times LCDs were issued
56	22
24	23
5	29
43	27
41	22
18	29
40	32
9	48
1	20
13	17
14	14
24	23
6	29
20	29
30	38
50	51
17	54
23	48
47	45
29	53
48	23
33	11
7	34
10	37
45	45
22	63
36	28
30	30
52	23
54	25
21	31
82	26
48	35
49	36
27	35
2	34
51	35
12	37
11	29
16	63
42	30
44	22
15	27
3	31
4	35
26	37
53	26
28	26
29	26
46	25
19	31
8	42
38	34
30	32
31	63
35	35
58	26
29	33

Exponential	Intercept	Slope	R-squared
1.00000000	15.3870994	0.99999999	16.44058271
2.91938E-06	0.14233592	2.86141E-06	0.116878113
0.00000000	0.30282884	0.00000000	0.328883128
0.00000000	5.71387227	0.179198867	8.870868144

Linear	Intercept	Slope	R-squared
7.5834E-09	16.4041993	0.7300E-09	17.01643271
2.7430E-05	2.24739026	4.8574E-05	3.74930179
0.00000000	6.39504950	0.00000000	5.16018170
0.017533819	22.1130029	1.51384843E-04	6.4
0.719249079	22.1130029	-0.16637603	1.65400767

Pearson product-moment correlation coefficient
0.99999999
-0.20619796

Pearson product-moment correlation coefficient
0.99999999
-0.08292072

Pearson product-moment correlation coefficient
0.99999999
-0.15180951

Pearson product-moment correlation coefficient
0.99999999
-0.26881488

Pearson product-moment correlation coefficient
0.99999999
-0.28870714

Table 9. Regressions for Sub-analysis

Analysis between all selected states

Subanalysis - East Coast, Center and West Coast

State	Number of Schools of Medicine (AAMC)	Number of times LCD=NCD	Number of Schools of Medicine (AAMC)	Number of times LCD different from NCD	Number of Schools of Medicine (AAMC)	Total number of times LCDs were issued	Number of physicians (1)	Number of times LCD=NCD	Number of physicians (1)	Number of times LCD different from NCD	Number of physicians (1)	Total number of times LCDs were issued
Massachusetts	4	17	4	16	4	34	8550	17	8550	16	8550	31
New York	13	23	13	13	13	37	41030	23	41030	13	41030	37
Maryland	3	16	3	10	3	27	9020	16	9020	27	9020	27
Georgia	4	10	4	10	4	29	3890	12	3890	10	3890	23
Florida	6	16	6	26	6	43	18930	16	18930	26	18930	43
Illinois	7	26	7	24	7	54	12630	29	12630	24	12630	54
Missouri	4	14	4	13	4	28	4190	14	4190	13	4190	26
Texas	8	19	8	15	8	29	17820	13	17820	15	17820	29
California	8	12	8	16	8	28	21820	12	21820	16	21820	29
Oregon	1	12	1	9	1	22	4250	12	4250	9	4250	22
Washington	1	12	1	9	1	22	4530	12	4530	9	4530	22

Model	Intercept	Residual	Model	Intercept	Residual	Model	Intercept	Residual	Model	Intercept	Residual	
Exponential	1.04455513	12.12425701	1.051657375	10.48282112	1.046135515	23.64337942	1.000012061	13.04088671	1.000012061	11.68853738	1.000012419	25.76467524
R ²	0.023744275	0.1406677	0.05019534	0.191186967	0.001917364	0.138774948	7.720398E-06	0.12235652	1.006956E-05	0.172824839	7.346299E-06	0.126603351
F	0.275184428	0.26308969	0.236744402	0.336979795	0.336965706	0.242597527	0.21515855	0.274277468	0.137219536	0.3398139452	0.238234761	0.262268283
Degrees of freedom	9	9	9	9	9	9	9	9	9	9	9	9
Regression ss	0.23769646	0.622945528	0.315955901	1.021996441	0.275271788	0.532451551	0.183591802	0.577053185	0.183591802	1.154368358	0.194672903	0.519052431
Linear	0.788651314	11.77950204	0.554014509	11.12846715	1.440875912	23.0680292	0.002208513	13.20895458	0.000156789	10.51089916	0.000367302	26.71983374
R ²	0.441901398	2.739003977	0.499147929	3.160474029	0.708027441	5.053344084	0.000145696	2.487787987	0.000162708	2.789438097	0.000205708	4.566112385
F	0.290314894	4.93161672	0.189136031	5.570487638	0.265871102	8.906762241	0.186396647	5.176072648	0.096599536	5.786448266	0.176081503	8.441481336
Degrees of freedom	9	9	9	9	9	9	9	9	9	9	9	9
Regression ss	77.11240976	218.9857912	53.27246184	279.2729927	258.5717319	715.9737226	54.87444745	241.1255526	31.82321518	300.7222394	170.2747252	862.2707293

State	GDP per capita (2)	Number of times LCD=NCD	GDP per capita (2)	Number of times LCD different from NCD	GDP per capita (2)	Total number of times LCDs were issued	Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Number of times LCD different from NCD	Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Number of times LCD	Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Total number of times LCDs were issued
Massachusetts	48296	17	46288	16	48296	31	7	17	7	17	7	31
New York	49499	23	49499	13	49499	37	12	23	12	23	12	37
Maryland	38205	16	38205	10	38205	27	10	16	10	16	10	27
Georgia	34017	10	34017	10	34017	23	24	10	24	10	24	23
Florida	32925	16	32925	26	32925	43	14	16	14	16	14	43
Illinois	40036	26	40036	24	40036	54	17	26	17	26	17	54
Missouri	32779	14	32779	13	32779	28	32	14	32	14	32	28
Texas	39044	19	39044	15	39044	29	28	19	28	19	28	29
California	42664	12	42664	16	42664	29	18	12	18	12	18	29
Oregon	38801	12	38801	9	38801	22	44	12	44	12	44	22
Washington	40027	12	40027	9	40027	22	33	12	33	12	33	22

Model	Intercept	Residual	Model	Intercept	Residual	Model	Intercept	Residual	Model	Intercept	Residual	
Exponential	1.00001424	8.55013162	0.998867441	10.57007136	1.00002097	20.71329929	0.98548324	20.97354295	0.984411948	18.27953305	0.984895994	42.02755840
R ²	1.62818E-05	0.852734529	2.1563E-06	0.885150598	1.86807E-05	0.678902167	0.067226767	0.17320372	0.009625569	0.828288794	0.00818104	0.183118306
F	0.181718921	0.283129801	0.01182271	0.38805111	0.04989606	0.295382596	0.912744726	0.356399727	0.232213942	0.317846598	0.303891719	0.241469179
Degrees of freedom	9	9	9	9	9	9	9	9	9	9	9	9
Regression ss	0.139180578	0.721462393	0.001986535	1.330973806	0.028450782	0.786272317	0.589162183	0.591484785	0.310691812	1.082126713	0.877999515	0.629763388
Linear	0.000276302	1.087178909	-0.001116003	19.22861448	0.00039044	21.31510143	-0.288309952	21.11338015	-0.225769175	16.48103892	-0.484105157	41.50357802
R ²	0.000240909	12.18890720	0.00034742	13.88524889	0.000616037	23.65801388	0.140773912	2.748247398	0.103919028	3.688977349	0.248930024	6.965323948
F	0.14470954	5.30269542	0.012213262	6.041396846	0.01090836	10.25649378	0.241595798	4.99426317	0.102934511	5.495029989	0.78779447	8.297346588
Degrees of freedom	9	9	9	9	9	9	9	9	9	9	9	9
Regression ss	1.302878116	42.8573224	0.061129879	328.4833248	0.018095442	901.0296351	2.868411703	901.0296351	2.1541514	34.78276504	34.78276504	701.4238663

Analysis between regions

By Region

	Number of Schools of Medicine (AAMC)	Number of times LCD=NCD	Number of Schools of Medicine (AAMC)	Number of times LCD different from NCD	Number of Schools of Medicine (AAMC)	Total number of times LCDs were issued	Number of physicians (1)	Number of times LCD=NCD	Number of physicians (1)	Number of times LCD different from NCD	Number of physicians (1)	Total number of times LCDs were issued
East Coast	6	17	6	15	6	33	81,896	84	81,200	75	81,200	165
Center	6	19	6	17	6	37	34,810	86	34,810	50	34,810	111
West Coast	3	12	3	11	3	24	30,610	36	30,610	34	30,610	75
Exponential												
slope	1.149335838	7.518431805	1.138123662	7.362051370	1.157755048	16.75408751	1.000013259	28.869060289	1.000012271	27.92249467	1.000012693	59.06833423
intercept	0.018023242	0.037182007	0.021189295	0.168173865	0.023679287	0.127673616	6.80943E-06	0.365705288	6.58371E-06	0.357449932	6.44959E-06	0.350190076
R ²	0.983508364	0.041910846	0.943040709	0.072527069	0.947431778	0.058066416	0.791264661	0.273783008	0.776494306	0.264717618	0.794762659	0.259341162
F	59.6367967	1	16.14330265	1	29.79477848	1	2.791386281	1	2.47295877	1	3.572483301	1
Regression ss	0.164753565	0.001756527	0.088072709	0.00200175	0.090044596	0.00203198	0.284214335	0.074902931	0.243439101	0.070075415	0.250449509	0.06727838
Linear												
slope	2.060273973	5.068018899	1.769273973	5.363013599	3.820547845	11.42622741	0.000795531	19.82291037	0.000671425	20.71313705	0.001507458	42.01398044
intercept	0.360049190	1.944618	0.533851276	2.878546382	0.694457472	4.823164382	0.000295767	15.94954279	0.00026769	14.50574457	0.000558458	30.32041822
R ²	0.976269306	0.838940934	0.916770093	1.241429853	0.848032699	2.030049407	0.883001313	11.8117938	0.862847121	10.78339249	0.879319479	22.45446887
F	10.836072581	1	10.807298337	1	18.240966822	1	7.339448488	1	6.291133899	1	7.296941417	1
Regression ss	22.95297318	0.708318113	16.75520041	1.54103589	78.92665815	4.326866784	1023.146184	139.5184728	726.8180315	115.8384651	9676.796763	504.203217

	GDP per capita (2)	Number of times LCD=NCD	GDP per capita (2)	Number of times LCD different from NCD	GDP per capita (2)	Total number of times LCDs were issued	Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Number of times LCD=NCD	Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Number of times LCD different from NCD	Ranking (Number of Level 1 and 2 Trauma Centers adjusted for population density)	Total number of times LCDs were issued
East Coast	40,747	84	40,747	75	40,747	164	67	84	67	75	67	164
Center	36,843	56	36,843	52	36,843	111	77	56	77	50	77	111
West Coast	40,424	34	40,424	34	40,424	73	92	34	92	30	92	73
Exponential												
slope	1.000010408	39.72472688	1.000006331	39.71332291	1.000010762	71.9682041	0.067014512	774.2081054	0.069143203	692.1408677	0.069481505	1965.562056
intercept	0.000239837	7.807668991	0.000187613	7.306822897	0.000191819	7.551563961	0.000331184	0.240638943	0.000269595	0.180057754	0.000244436	0.240728169
R ²	0.000836282	0.998500990	0.001144752	0.999020259	0.001144584	0.971566397	0.99188869	0.993937054	0.992797146	0.940367748	0.991100416	0.993998184
F	0.002690501	1	0.001145484	1	0.001144503	1	122.2846447	1	191.0022141	1	111.3000873	1
Regression ss	0.000963724	0.339813483	0.000356715	0.313128801	0.001630504	0.328678942	0.358263888	0.002913396	0.311883346	0.00162117	0.324745163	0.002512804
Linear												
slope	0.001862598	-18.60959698	0.001436135	-2.483095872	0.000697884	-29.56036595	-1.678684211	206.0631579	-1.605263156	179.9473884	-3.502631578	595.4736842
intercept	0.011241887	43.8118504	0.008387799	378.3548469	0.011259556	841.4810291	0.439110600	31.89147786	0.300892677	29.96629824	0.756632721	60.62725555
R ²	0.028472148	33.58167132	0.014225335	28.78016117	0.001181754	63.68941765	0.958180389	7.13774853	0.966071948	5.332300897	0.958688551	13.46437790
F	0.030367133	1	0.021891504	1	0.029992087	1	21.82093664	1	28.47413029	1	22.0401553	1
Regression ss	34.80628458	1128.400382	18.09489555	826.3712671	121.6681566	4060.341644	1111.719298	50.94739842	816.0087719	28.66789474	3996.710026	181.2894737

Analysis within regions

Within region	Number of Schools of Medicine (AAMC)	Number of times LCD=NCD	Number of Schools of Medicine (AAMC)	Number of times LCD different from NCD	Number of Schools of Medicine (AAMC)	Number of times LCDs were issued	Number of physicians (1)	Number of times LCD=NCD	Number of physicians (1)	Number of times LCD different from NCD	Number of physicians (1)	Number of times LCDs were issued
East Coast												
Exponential												
slope	1.045413849	12.52293559	0.01367666	12.91845726	1.02178569	20.23240322	1.000013174	12.12371261	1.000005184	12.66939157	1.000019525	26.84304492
r2	0.033338457	0.181840520	0.055932082	0.39275066	0.000096541	0.214611032	4.27758E-06	0.000043232	1.50713E-05	0.317456213	7.60368E-06	0.160161192
F	5.186420225	3 Degrees of freedom	0.019240941	0.454889947	0.05812784	0.248556649	0.775061405	0.120803148	0.053135588	0.446903148	0.390780454	0.225496495
Regression ss	0.733899692	0.073389969	0.098935254	0.3	1.045922757	0.3	10.33697829	0.3	0.186332253	0.3	1.816102325	0.3
		residual ss	0.012178015	0.620774592	0.084682218	0.185354943	0.186204665	0.048297114	0.023635347	0.599320961	0.057421253	0.152546003
Linear												
slope	0.833333333	11.8	0.136363636	14.18181818	0.99890697	26.98181818	0.00244627	12.79701746	0.00244627	12.79701746	0.00244627	27.48389169
r2	0.29272846	0.265280204	0.038616121	0.590003039	0.091445398	0.894445391	6.2098E-05	1.307804953	0.000254084	5.251850583	0.00024624	5.180730021
F	8.104125737	3 Degrees of freedom	0.006971714	7.632665049	0.245450504	7.973991124	0.838038208	1.841328932	0.032173074	7.535196061	0.367156278	7.302577008
Regression ss	45.85333333	16.96666667	1.227272727	174.7727273	0.978106745	3	15.52298723	3	0.069777777	3	1.740556853	3
		residual ss	0.046336353	0.157422214	0.026945227	0.244603773	52.62879948	10.17120051	5.862490958	170.527535	62.81170714	159.9828929
Central												
Exponential												
slope	1.042651135	11.35417594	1.077438358	10.42322397	1.058816151	24.53545424	1.000004207	16.81996389	1.000017181	13.70270398	1.000010774	81.14047277
r2	0.038450984	0.614878588	0.10411065	0.39676559	0.187989548	1.101640153	6.35672E-05	0.825630387	4.310E-05	0.556201359	3.20696E-05	0.675719517
F	0.03998584	3 Degrees of freedom	0.234917738	0.39676559	0.10411065	0.494574335	0.004666666	0.625488523	0.137077708	0.421320207	0.040179229	0.511917683
Regression ss	0.01518711	0.378075678	0.046336353	0.157422214	0.102895272	0.244603773	0.005059293	1	0.158853007	1	0.041857923	1
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353	0.157422214	0.219250752	23.11538452	0.001275701	17.187231	0.000271328	14.18529947	0.000598626	32.37226047
		residual ss	0.046336353									

Table 10. MEDCAC Analysis

Name	MD (0=No, 1=Yes)	Other degrees	Academic (1)/Non-academic (0)	Specialty	Age	State	University/Hospital	Industry or Academy/Hospital (0=Industry, 1=Academy)	Sex (0=Female, 1=Male)
Ray Baker	1		1	Anesthesiology	51	Washington	University of Washington	1	1
Michael Blaivas	1	1 RDMS	1	Emergency Medicine		Georgia	Northside Hospital, Forsyth	1	1
Ross Bogay	0	0 DO	1	Physical medicine and rehabilitation		Illinois	Northwestern University Feinberg School of Medicine	1	1
Patricia A. Bombo	1	1 FACP	0	NA		New York	Excelsus Blue Cross Blue Shield	0	0
Kevin J. Bozik	1	1 MBA	1	Orthopaedic Surgery		California	University of California, San Francisco School of Medicine	1	1
Raul Brayten	1		1	Hematopathology		Florida	Cars Diagnostics	0	1
Virginia C. Calega	1	1 MBA	0	Internal Medicine and Geriatrics		Pennsylvania	Highmark Inc. (Medicare Carrier)	0	0
Charles S. Carignan	1		0	General Surgery		Maryland	Novesys Medical, Inc.	0	1
Mark D. Carlson	1	1 MA	0	Cardiology	55	Minnesota	St. Jude Medical	0	1
John Chae	1		1	Physical medicine and rehabilitation		Ohio	MetroHealth Medical Center	1	1
Catherine Cheng	1	1 FACP	1	Internal Medicine	47	California	On Lok Senior Health Services	0	0
Joseph P. Curtis	1		1	Internal Medicine, Cardiology	38	Connecticut	Yale University School of Medicine	1	NA
Marion Danis	1		1	Internal Medicine		Maryland	NIH Clinical Center	1	0
Helen Darling	0	0 MA	0	NA		District of Columbia	National Business Group on Health	0	0
Charles Davis	1	1 PhD	1	Orthopaedic Surgery		Pennsylvania	The Milton S. Horshey Medical Center	1	1
William T. Denman	1		1	Anesthesiology		Massachusetts	Massachusetts General Hospital	1	1
Roger Dmochowski	1		1	Urology and Surgery		Tennessee	Vanderbilt University	1	1
Mark H. Ebell	1	1 MS	1		46	Georgia	University of Georgia	1	1
Josef E. Fischer	1		1	Surgery		Massachusetts	Harvard Medical School	1	1
Clifford Goodman	0	0 PhD	0	NA		Virginia	The Lewin Group	1	1
Philip B. Gorelick	1	1 MPH	1	Neurology		Illinois	University of Illinois at Chicago College of Medicine	1	1
Leslie Grammer	1		1	Allergy-Immunology		Illinois	Northwestern University Feinberg School of Medicine	1	0
Laura H. Gunn	0	0 PhD	1			Georgia	Georgia Southern University	1	0
Steve Gutman	1	1 MBA	1	Pathology		Illinois	Blue Cross Blue Shield Association Technology Evaluation Center	0	1
Willard K. Herms	1	1 MBA	1	Ophthalmology		Illinois	BlueCross BlueShield of Illinois	1	1
Paula E. Horlman-Stein	0	0 PhD	1	Psychology		Ohio	Center for Healthy Aging	1	0
Daniel F. Hayes	1		1	Breast Oncology		Michigan	University of Michigan Comprehensive Cancer Center	1	1
I. Craig Henderson	1		1	Hematology/Oncology		California	University of California, San Francisco School of Medicine	1	1
Peter Hesselstine	1		1	Internal Medicine, Infectious Disease	63	California	Beckman Coulter, Inc.	0	1
James M. Hevezi	0	0 PhD	1	Medical Physics	70	Florida	CyberKnife Center of Miami	0	1
Alice Jacobs	1		1	Cardiology	65	Massachusetts	Boston Medical Center	1	0
Saire A. Jan		1 MS, PharmD	1	NA		New Jersey	Horizon Blue Cross Blue Shield of NJ	0	0
Jeffrey G. Jarvick	1	1 MPH	1	Radiology and Neurosurgery		Washington	University of Washington Medical Center	1	1
Sarah H. Kagan	0	0 PhD, RN	1	NA		Pennsylvania	University of Pennsylvania School of Nursing	1	0
Norman S. Kato	1		1	Thoracic Surgery	54	California	Cardiac Care Medical Group, Inc.	0	1
Karen Kaul	1	1 PhD	1	Pathology	55	Illinois	NorthShore University HealthSystem Evanston Hospital	1	0
Edward Kim	1	1 MBA	1	Psychiatry	48	New Jersey	Eisai, Inc.	0	1
Roger D. Klein	1	1 JD	1	Pathology	43	Wisconsin	Molecular Oncology BloodCenter of Wisconsin	1	1
Bruce Lett	1		1	Geriatrics	50	Maryland	Johns Hopkins University School of Medicine	1	1
Susan A. Levine	0	0 DVM, MS, PhD	1	Pharmacology	60	Pennsylvania	Hayas, Inc.	0	0
Courtland G. Lewis	1		1	Orthopedic Surgery	57	Connecticut	Orthopaedic Associates of Hartford, PC	0	1
Frederick A. Masoudi	1	1 MSPH	1	Cardiology	45	Colorado	Denver Health Medical Center	1	1
Karl Mattszewski	0	0 MS, PharmD	1	Pharmacology	56	Illinois	Elsevier/Gold Standard	1	1
Robert McDonough	1	1 JD	1			Connecticut	National Medical Services Aetna, Inc.	0	1
Barbara McNeil	1	1 PhD	1	Radiology	69	Massachusetts	Harvard Medical School	1	0
Diane E. Maier	1		1	Geriatrics		New York	Mount Sinai School of Medicine	1	0
Pater Metropoulos	0	0 DO, MPH, FACC	0	Occupational Medicine	45	Michigan	Independent Medical Consultants, Benchmark Health, OccuNET	0	1
David M. Mintzer	1		1	Hematology/Oncology	55	Pennsylvania	University of Pennsylvania	1	1
Theresa Makiman	1		1	Psychiatry	45	New Jersey	University of Medicine & Dentistry of New Jersey	1	0
Arden M. Morris	1	1 MPH	1	Surgery		Michigan	University of Michigan	1	0
Mauric Mosconi	1		1	Cardiology	50	Florida	University of Miami Miller School of Medicine	1	1

Name	MD (0=No, 1=Yes)	Other degrees	Academic (1)/Non-academic (0)	Specialty	Age	State	University/Hospital	Industry or Academy/Hospital (0=Industry, 1=Academy)	Sex (0=Female, 1=Male)
Sharon-Lisa T. Normand	0	PhD	1	Biostatistics	46	Massachusetts	Harvard Medical School	1	0
Parashar B. Patel	0	MPA	0	NA		Massachusetts	Boston Scientific	0	1
Stephen Pauker	1	MACP, FACC	1	Cardiology	67	Massachusetts	Tufts Medical Center	1	1
William R. Phillips	1	PhD	1	Family medicine	56	Washington	University of Washington	1	1
Leonard M. Pogach	1	MBA, FACP	1	Endocrinology		New Jersey	Veterans Health Administration	1	1
Louis Potters	1	FACR	1	Prostate cancer/Radiation Oncology		New York	North Shore - Long Island Jewish Health	1	1
James E. Pucklin	1		1	Ophthalmology	69	Michigan	Wayne State University School of Medicine	1	1
Juan Quintana	0	CRNA, DNP					Sleepy Anesthesia Associates, PLLC	0	1
Thomas Ratko	0	PhD	1	Pharmacology	55	Illinois	Blue Cross Blue Shield Association	0	1
Prabashri Reddy	1						Technology Evaluation Center	0	1
Matnew J. Reeves	0	BVSc, MS, PhD	1	Epidemiology		Michigan	Independent Consultant	0	NA
Ryan H. Saadi	1	MPH	1	Health Outcomes		New York	College of Human Medicine	1	1
Ralph Secco	1	MS	1	Neurology	52	Florida	CORDIS Corporation, Johnson & Johnson	0	1
David J. Samson	0	MS	1	Preventive Medicine		Illinois	University of Miami Miller School of Medicine	1	1
Saty Setya-Murti	1	FAAN	1	Neurology		Kansas	Blue Cross and Blue Shield Association	0	1
Maren T. Scheuner	1	MPH	1	Internal Medicine		California	Health Policy Consultant	0	1
J. Sanford Schwartz	1		1	Internal Medicine	58	Pennsylvania	RAND Corporation and VA Greater Los Angeles	1	0
Elaine M. Scorzi	0	MSN RN, APRN	1	Psychiatry Nurse		Illinois	University of Pennsylvania	1	1
Deborah Shatin	0	PhD	1	Sociology		Minnesota	Rush University Medical Center	1	0
Paul R. Skorzynski	1	RDMS	1	Emergency Medicine		Delaware	Shelin Associates, LLC	0	0
Eric Z. Sitten	1	MSHA, MA	1	Internal Medicine/Emergency Medicine	57	New York	Christiana Care Health System	0	1
Ajay Singh	0	MBBS, FRCP, M	1	Neurology		Massachusetts	Philips Healthcare	0	1
Gurkirpal Singh	1		1	Gastroenterology		California	Brigham and Women's Hospital, Stanford University School of Medicine	1	1
Andrew Sloan	1	FACS	1	Neurosurgery	47	Ohio	Stanford University School of Medicine	1	1
John Spertus	1	MPH	1	Cardiology	45	Missouri	University Hospitals of Cleveland	1	1
Robert L. Steinbrook	1		1	Family medicine		New Hampshire	University of Missouri	1	1
Steven Teutsch	1	MPH	1	Epidemiology		California	Dartmouth Medical School	1	1
Marita Teter	0	PhD, RN, FAAN	1			California	LA County Public Health Department	1	1
James C. Tsai	1	MBA, FACS	1	Ophthalmology		Michigan	University of Michigan Health System	1	0
Craig Umschaid	1	MSCE	1	Internal Medicine	36	Pennsylvania	Yale University School of Medicine	1	1
Michael B. Wallace	1	MPH	1	Gastroenterology	44	Florida	University of Pennsylvania School of Medicine	1	1
Jed I. Weissberg	1		1	Internal medicine/Gastroenterology		California	College of Medicine Mayo Clinic	1	1
David P. Winchester	1	FACS	1	Breast Oncology	69	Illinois	The Permanente Federation, LLC	0	1
Ying Xie	0	PhD, MS	1	Immunology		Indiana	Evansston Hospital	1	1
Way Yin	1		1	Anesthesiology	48	Washington	Bioset, Inc.	0	1
Cherie Y. Zachary	1		1	Internal medicine/Allergy and Immunology	49	Minnesota	Bellingham Spine Pain Specialists, PS	0	1
Patient Advocates							Minnesota Allergy & Asthma Consultants, PLLP	0	0
Mindy L. Aisen	1					District of Columbia	United Cerebral Palsy Research and Education Foundation	1	0
Phyllis Atkinson	0	RN, MS, GNP-B	1			Ohio	Advanced Geriatric Education & Consulting, LLC	1	0
Diane E. Dorman	0					Connecticut	National Organization for Rare Disorders	1	0
Susan Kendig	0	JD, MSN				Missouri	University of Missouri-St. Louis	1	0
Curtis A. Mock	1	MBA	0	Family medicine		Tennessee	UnitedHealthcare	0	1
Teresa M. Schroeder	0	BS, MBA	1			New York	Musculoskeletal Clinical Regulatory Adv	0	0
Industry Representatives									
Peter Juhn	1	MPH	0	Internal Medicine		New Jersey	Therapeutic Resource Centers Medco Health Solutions, Inc.	0	1
Lester D. Paul	1	MS	0			District of Columbia	Clinical and Scientific Affairs National Pharmaceutical Council	0	1
Eleanor M. Perlatto	0	PhD, MS	0	Health Policy/Epidemiology		New York	Pfizer, Inc.	0	0
G. Gregory Raab	0	PhD	0	Public Policy			Health Policy Consultant Raab Associates	0	1
Brian Saal	0	PhD	0			New Jersey	Sanofi Aventis, US	0	1
Noel Thomas	0	PhD	0			New York	Pfizer Inc.	0	1
Total	69		78		53			58	67

Table 11. Some States and their Medicare Contractors

States with higher number of LCDs	Medicare Contractor Part A/Part B	States with lower number of LCDs	Medicare Contractor Part A/Part B
Virginia	Palmetto GBA	Idaho	National Heritage Insurance Corporation
West Virginia	Palmetto GBA	Alaska	National Heritage Insurance Corporation
Illinois	Noridian Administrative Services, LLC	Arizona	Noridian Administrative Services, LLC
Wisconsin	Noridian Administrative Services, LLC	Oregon	National Heritage Insurance Corporation
Ohio	Highmark Medicare Services Inc.	Washington	National Heritage Insurance Corporation
Michigan	National Government Services	Alabama	Cahaba GBA
Kentucky	Highmark Medicare Services Inc.	Georgia	Cahaba GBA
Indiana	National Government Services	Mississippi	Pinnacle Business Solutions Inc.
Connecticut	National Government Services	Tennessee	Cahaba GBA
		New Jersey	Highmark Medicare Services Inc.
		DC	Highmark Medicare Services Inc.
		Montana	Noridian Administrative Services, LLC
		North Dakota	Noridian Administrative Services, LLC
		South Dakota	Noridian Administrative Services, LLC
		Utah	Noridian Administrative Services, LLC
		Wyoming	Noridian Administrative Services, LLC

States with higher number of LCDs different from NCDs	Medicare Contractor Part A/Part B	States with higher number of LCDs equal to NCDs	Medicare Contractor Part A/Part B
Virginia	Palmetto GBA	Virgin Islands	First Coast Service Options Inc.
West Virginia	Palmetto GBA	Florida	First Coast Service Options Inc.
Ohio	Highmark Medicare Services Inc.	Illinois	Noridian Administrative Services, LLC
Kentucky	Highmark Medicare Services Inc.	Michigan	National Government Services
Illinois	Noridian Administrative Services, LLC	North Carolina	Palmetto GBA
Michigan	National Government Services	Wisconsin	Noridian Administrative Services, LLC
Indiana	National Government Services	West Virginia	Palmetto GBA
Connecticut	National Government Services	Ohio	Highmark Medicare Services Inc.
Kansas	Wisconsin Physician Services Health Insurance Corporation	Kentucky	Highmark Medicare Services Inc.
New York	National Government Services	South Carolina	Palmetto GBA
		Indiana	National Government Services
		Connecticut	National Government Services

VIII. Appendix A.

Interviews with Contractor Medical Directors (CMDs)

Interview 1. Dr. George Waldmann, former Contractor Medical Director of Noridian Administrative Services, Medicare Part B. August, 2010

1. According to your experience, are the majority of LCDs for a specific procedure issued before the corresponding NCD? Do NCDs come later after the necessity to have a policy becomes national?

Many LCDs are issued before NCDs. Once many contractors have issued a series of LCDs describing the same procedure, CMS often considers the necessity to issue a NCD. The original idea of LCDs was to have a mechanism to respond to coverage issues specific to a location.

2. What are the main reasons to issue an LCD in the cases where there is already an NCD?

If there is already an NCD in place, the main reason to issue an LCD is to define the CPT and ICD-9 codes that apply to the procedure. I have suggested to CMS that they should issue the covered ICD-9 codes together with the NCD in order for all contractors to have the same covered codes at the national level. Unfortunately, today different contractors may apply different codes for the same procedures. One example is PET Scan policies, where codes and LCDs present a significant degree of variation among contractors.

3. According to the Medicare Program Integrity Manual Chapter 13-Local Coverage Determinations (04-25-08) "the DME MACs shall ensure that the adopted LCDs are identical among the DME MACs". Why is consistency between LCDs (by different MACs) required for Durable Medical Equipment and not for other benefit categories?

Consistency is required for DME MACs because they are only four and administratively is not difficult to achieve it this consistency. For other benefit categories it is not done because it is difficult to coordinate among multiple contractors.

4. According to my analysis (based on the CMS Coverage Database), there is consistency between different DME MACs LCDs (all are the same), however, LCD criteria and limitations differ from NCDs in many cases. For other benefit

categories LCDs coverage criteria and limitations differ between MACs and between LCDs and NCDs. According to your opinion, what do you think are the causes of these discrepancies if LCDs shouldn't differ from NCDs? (In most of the cases, LCDs narrow the criteria or change limitations without necessarily contradicting the NCD)

5. According to the same manual, "When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors shall allow for individual consideration unless the LCD supports automatic denial for some or all of those other diagnoses/conditions". Most of the discrepancies between NCDs and LCDs that I have detected in my study are of this type (the NCD didn't exclude coverage for certain diagnosis or conditions while the LCD did). Why do you think this happens?

4, 5. Most LCDs are issued as a mechanism to restrict or describe coverage, using CPT and ICD-9 codes. Without an LCD, contractors can't deny a claim automatically, but it must be done on a case-by-case basis, which administratively requires personnel time and other resources, significantly increasing costs to contractors. Thus, LCDs are issued to reduce contractor's administrative costs and reduce claim errors. Discrepancies between LCDs and NCDs can occur because NCDs are often less specific about covered conditions and limitations and LCDs specify them with specific codes.

6. According to my analysis, some states are more active in issuing LCDs. Which do you think are the main drivers of LCD issuing activity?

The main drivers of LCD activity are:

- The main reason is to limit payment to medically necessary diagnoses and conditions by automating legitimate denials.
- A history of abuse and fraud. LCDs are issued to be very specific about coverage conditions and limitations to avoid payment for areas of abuse and fraud.
- The Contractor Medical Director (CMD) specialty. Some times LCDs will be issued in the medical specialty or area of expertise of the CMD.
- More LCDs will be issued in states where contractors have assigned more personnel to creating and maintaining LCDs. Although CMS used to encourage large numbers of LCDs this doesn't seem to be the case any more.
- New procedures, to educate and assist physicians when they are submitting incorrect claims

7. In your opinion, does the current model to issue LCDs taking into account the input from the Carrier Advisory Committee (CAC) from each state work? Does the CAC reflect state-by-state medical practice differences when issuing LCDs? Are these differences desirable? How does the CAC prioritize for which procedures is an LCD required?

Some CACs are more interactive than others and some contractors give much importance to the CAC-submitted LCD comments than others. The utility of having a CAC per state is not so great because in the end LCDs don't seem to reflect state-by-state differences in medical practice. CACs are also a cost to CASC members who must travel and take time away from their practices with no remuneration for attending the CAC. These costs in time and money invested in CACs make it difficult for CMDs to convince physicians to join CACs. In many cases the physicians who join are not opinion leaders in their specialties. For these and other reasons CMS and contractors may be moving toward having only a single CAC for each jurisdiction.

8. Why do some contractors issue LCDs only for some states of their jurisdiction and not all?

I haven't seen this happen.

9. In your opinion, does Medicare Contractor Reform will cause more homogeneous policies between states or more divergent ones?

Yes, Medicare Contractor Reform should produce more homogeneous policies due to decreasing numbers of Medicare contractors and increasing the numbers of states within each contractor jurisdiction.

10. Did you have an experience of issuing an LCD that challenged the standard of practice? Did the LCD have to be changed later?

Yes, I and other CMDs have personally experienced a lot of pressure from consumers and industry when policies have restricted coverage due to questionable efficacy and a lack of published evidence for the procedure.

11. According to the Medicare Program Integrity Manual, "Contractors shall implement new Least Costly Alternative (LCA) determinations through an LCD. "Least Costly Alternative" is a national policy provision that shall be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principle to payment for

non-DME services as well". Why is the LCA principle mandatory only for DME and not for other benefit categories?

The "Least Costly Alternative" (LCA) principle is very difficult to implement because of pressure from industry and patients. Also, courts have recently ruled against LCAs and contractors have had to rescind previously existing LCA LCDs.

12. According to my analysis, from 193 procedures with NCDs currently in effect (from the following benefit categories: Inpatient Hospital Services, Durable Medical Devices, Diagnostic Laboratory Tests, Physician Services and Diagnostic Tests), only 10 required Technology Assessments and only 12 required a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), leaving the majority of national decisions to the discretion of CMS authorities. According to your opinion, should there be more decisions based on Technology Assessments and MEDCACs? What is the main reason most decisions are not based on them?

I suppose the main reason is that CMS has limited resources and Technology Assessments and MEDCACs are costly. This is also the reason why a lot of the policy activity is carried on at the local level, primarily because LCDs can be implemented faster than NCDs. However, the level of expertise at the local level is usually less than at the national level. Also the evaluation mechanism is more structured and slower at the national level. In my experience, the medical device and drug industries prefer to try to convince local contractors of the benefits of their technologies at the local level instead of CMS, because it is easier in terms of evidence required and time invested. Once a contractor issues a policy in favor of a procedure, other contractors are pressured to do the same.

Do you allow that your opinions appear on my thesis, which will be a publicly available document?

Yes

Do you want to maintain your identity as confidential while allowing your opinions to appear on my thesis?

I allow the disclosure of my identity

Interview 2. Contractor Medical Director, August 2010

1. According to your experience, are the majority of LCDs for a specific procedure issued before the corresponding NCD? Do NCDs come later after the necessity to have a policy becomes national?

Not necessarily. The issuing process of NCDs and LCDs are independent of each other. Sometimes LCDs are issued before NCDs (or without any NCD) and sometimes the NCD is issued first.

2. What are the main reasons to issue an LCD in the cases where there is already an NCD?

To specify the billing codes (which are not specified in NCDs) and to define the circumstances under which automatic coverage denials apply.

3. According to the Medicare Program Integrity Manual Chapter 13-Local Coverage Determinations (04-25-08) "the DME MACs shall ensure that the adopted LCDs are identical among the DME MACs". Why is consistency between LCDs (by different MACs) required for Durable Medical Equipment and not for other benefit categories?

Because many of the DME suppliers operate nationwide and in that way there is no discrimination for access to them among beneficiaries from different regions.

4. According to my analysis (based on the CMS Coverage Database), there is consistency between different DME MACs LCDs (all are the same), however, LCD criteria and limitations differ from NCDs in many cases. For other benefit categories LCDs coverage criteria and limitations differ between MACs and between LCDs and NCDs. According to your opinion, what do you think are the causes of these discrepancies if LCDs shouldn't differ from NCDs? (In most of the cases, LCDs narrow the criteria or change limitations without necessarily contradicting the NCD).

The main difference between NCDs and LCDs is that NCDs apply nationally, where LCDs are at local contractor discretion and may address a variety of things, including clarification of an LCD, ie, specific codes, etc. LCDs specify exclusions (usually defining the billing codes allowed for coverage) not specified by NCDs, according to the contractor's specific requirements. For example, NCDs for PET Scans have caused a lot of

differences between contractors because each one defines different billing codes for the conditions mentioned in the NCD.

5. According to the same manual, "When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors shall allow for individual consideration unless the LCD supports automatic denial for some or all of those other diagnoses/conditions". Most of the discrepancies between NCDs and LCDs that I have detected in my study are of this type (the NCD didn't exclude coverage for certain diagnosis or conditions while the LCD did). Why do you think this happens?

Most of the differences between LCDs and NCDs are in the form of exclusions not specified in NCDs. This happens because NCDs don't specify billing codes and contractors determine exclusions according to their local circumstances, as long as they don't conflict with NCDs. This only applies to those NCDs and LCDs that address the same topic, of course.

6. According to my analysis, some states are more active in issuing LCDs. Which do you think are the main drivers of LCD issuing activity?

In no particular order...

- The economic and human resources that the contractor has available to issue LCDs. Contractors with more economic and human resources available for LCDs will usually issue more LCDs. Each LCD consumes resources not only when it is issued but also later because it has to be reviewed and enforced.

- Contractor's philosophy towards coverage policies. Some contractors prefer to leave the coverage decisions in the hands of physicians, others have a different approach to coverage decisions.

- How clear are the NCDs? Sometimes the contractor doesn't need a new LCD because the NCD is clear and serves its needs.

- Fraud. In states with a greater history of fraud, more LCDs are issued, to make clear the circumstances under which coverage will be automatically denied and in that way reduce fraud.

- Perceived need for an LCD. As examples and not all inclusive, in states with low population density, low number of Trauma Centers, low number of physicians and few or no Schools of Medicine, the need for LCDs may be lower than in states with the opposite characteristics.

7. In your opinion, does the current model to issue LCDs taking into account the input from the Carrier Advisory Committee (CAC) from each state works? Does

the CAC reflects state-by-state medical practice differences when issuing LCDs? Are these differences desirable? How does the CAC prioritize for which procedures is an LCD required?

The issuing of LCDs is not a democratic process, the decision is ultimately made by the contractor, mainly by the CMD. Usually the CMD consults with a variety of sources before the meeting with the CAC. CAC meetings take place approximately every four months. They last about two hours with approximately 30 physicians from the specialties impacted by the particular LCDs discussed in each meeting. Each LCD takes about 90 days to complete. I think that in the future there are going to be 1 or 2 CACs per contractor.

The CMD prioritizes which LCDs to issue according to the following criteria:

- New technologies that might pose a risk to the Medicare funds.
- Procedures with perceived overutilization
- Procedures where there is concern for abuse
- The number and type of claims received

8. Why do some contractors issue LCDs only for some states of their jurisdiction and not all?

Because in the past there were more contractors. After Contracting Reform, LCDs will be issued for all the states of the contractor's jurisdiction.

9. In your opinion, does Medicare Contractor Reform will cause more homogeneous policies between states or more divergent ones?

Contracting Reform will cause more homogeneous policies.

10. Did you have an experience of issuing an LCD that challenged the standard of practice? Did the LCD have to be changed later?

Yes, as long as the LCD is based on clinical evidence from respected journals or expert opinion, it will prevail. However, if other contractors cover a procedure that we don't cover, it will build pressure on us to cover it.

11. According to the Medicare Program Integrity Manual, "Contractors shall implement new Least Costly Alternative (LCA) determinations through an LCD. "Least Costly Alternative" is a national policy provision that shall be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principle to payment for

non-DME services as well". Why is the LCA principle mandatory only for DME and not for other benefit categories?

LCAs are not used anymore even for DMEs, mainly due to a court case/decision and legal pressure from the medical device and pharmaceutical industry.

12. According to my analysis, from 193 procedures with NCDs currently in effect (from the following benefit categories: Inpatient Hospital Services, Durable Medical Devices, Diagnostic Laboratory Tests, Physician Services and Diagnostic Tests), only 10 required Technology Assessments and only 12 required a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), leaving the majority of national decisions to the discretion of CMS authorities. According to your opinion, should there be more decisions based on Technology Assessments and MEDCACs? What is the main reason most decisions are not based on them?

TAs and MEDCACs are expensive, that's why they are only used in NCDs and even at a national level, they are used only for special cases. In addition to being costly, this process is lengthy, and many times there is insufficient evidence to sustain a majority consensus opinion.

Do you allow that your opinions appear on my thesis, which will be a publicly available document? Yes

Do you want to maintain your identity as confidential while allowing your opinions to appear on my thesis? Yes, absolutely.

Interview 3. Dr. Richard Baer, Contractor Medical Director, National Government Services, August 2010

1. According to your experience, are the majority of LCDs for a specific procedure issued before the corresponding NCD? Do NCDs come later after the necessity to have a policy becomes national?

There is not a direct correlation between the time frames for issuing NCDs and issuing LCDs. NCDs are issued to establish whether something is covered or not, and usually don't assign billing codes. LCDs define under which circumstances the items already covered by NCDs are reimbursed.

2. What are the main reasons to issue an LCD in the cases where there is already an NCD?

To assign billing codes and in that way automate coverage decisions in the computer system. Assigning billing codes at a national level would be too much work for CMS, so it lets contractors to decide on that.

3. According to the Medicare Program Integrity Manual Chapter 13-Local Coverage Determinations (04-25-08) "the DME MACs shall ensure that the adopted LCDs are identical among the DME MACs". Why is consistency between LCDs (by different MACs) required for Durable Medical Equipment and not for other benefit categories?

Since there are only four DME contractors, it is easier for them to agree on coverage policies. Instead of issuing NCDs, which is very costly to CMS, it allows DME contractors to issue LCDs, which are the same for all and would be the equivalent to issue an NCD. For other benefit categories, consistency is not required because when the whole coverage system was planned, the idea was to let contractors adapt coverage policies according to the local standards of medical practice. But now, there is no reason to have variation in medical practice across states, because medical practice is based on evidence and it should be the same at a national level.

4. According to my analysis (based on the CMS Coverage Database), there is consistency between different DME MACs LCDs (all are the same), however, LCD criteria and limitations differ from NCDs in many cases. For other benefit categories LCDs coverage criteria and limitations differ between MACs and between LCDs and NCDs. According to your opinion, what do you think are the causes of these discrepancies if LCDs shouldn't differ from NCDs? (In most of the

cases, LCDs narrow the criteria or change limitations without necessarily contradicting the NCD)

5. According to the same manual, "When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors shall allow for individual consideration unless the LCD supports automatic denial for some or all of those other diagnoses/conditions". Most of the discrepancies between NCDs and LCDs that I have detected in my study are of this type (the NCD didn't exclude coverage for certain diagnosis or conditions while the LCD did). Why do you think this happens?

4 and 5. I wouldn't call these discrepancies, since an LCD should never contradict an NCD. What an LCD does, is to define more precisely coverage exclusions not specified on an NCD, according to detected aberrant billing patterns by the contractor. CMS leaves these exclusion decisions open to the contractor's discretion. LCDs are different between different contractors or different states because sometimes more active members in the CACs influence the accepted billing codes according to their specialties.

6. According to my analysis, some states are more active in issuing LCDs. Which do you think are the main drivers of LCD issuing activity?

- Ambition of the CMD
- Staff available to the CMD for LCD issuing purposes
- More experienced CMDs are very active in issuing LCDs
- Contractors perform data analysis to detect aberrant billing patterns and compare utilization patterns between states (CMS doesn't perform these kind of analysis). These aberrant billing patterns drive LCD issuing activity.
- I think issuing more LCDs is good for physicians, contractors and CMS.

7. In your opinion, does the current model to issue LCDs taking into account the input from the Carrier Advisory Committee (CAC) from each state works? Does the CAC reflects state-by-state medical practice differences when issuing LCDs? Are these differences desirable? How does the CAC prioritizes for which procedures is an LCD required?

The current model works well. Is not that CACs reflect state-by-state medical practice differences, what happens is that CAC members have different levels of expertise. CMDs without enough staff or efficient CACs copy other contractor's LCDs.

The CAC doesn't set the priorities for issuing LCDs. The contractor through its CMD sets the priorities according to:

- Data analysis of medical review, overutilization and possible abuse. The CMD gives priority to procedures that represent a significant amount of money, that have significant clinical value or that pose a significant medical risk. Contractors issue about 6 to 8 LCDs per session, having 3 sessions per year.

8. Why do some contractors issue LCDs only for some states of their jurisdiction and not all?

The discrepancies between LCDs in different states that are serviced by the same contractor are due in the majority of cases to the state of affairs before Contracting Reform. Contractor's consolidation has homogenized LCDs that were previously issued by different contractors. In general, there is consistency between LCDs in states of the same jurisdiction.

9. In your opinion, does Medicare Contractor Reform will cause more homogeneous policies between states or more divergent ones?

There will still be differences between states belonging to different contractors but there will be no longer differences between Medicare Part A and Part B policies because they will be serviced by the same contractor.

10. Did you have an experience of issuing an LCD that challenged the standard of practice? Did the LCD have to be changed later?

When you challenge the standard of practice, you have to defend your position with strong evidence. However, when there is strong political pressure driven mainly from the industry, sometimes the contractor puts the LCD on hold.

11. According to the Medicare Program Integrity Manual, "Contractors shall implement new Least Costly Alternative (LCA) determinations through an LCD. "Least Costly Alternative" is a national policy provision that shall be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principle to payment for non-DME services as well". Why is the LCA principle mandatory only for DME and not for other benefit categories?

Due to recent legal issues, contractors no longer base their LCDs on LCAs.

12. According to my analysis, from 193 procedures with NCDs currently in effect (from the following benefit categories: Inpatient Hospital Services, Durable Medical Devices, Diagnostic Laboratory Tests, Physician Services and Diagnostic Tests), only 10 required Technology Assessments and only 12 required a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), leaving the majority of national decisions to the discretion of CMS authorities. According to your opinion, should there be more decisions based on Technology Assessments and MEDCACs? What is the main reason most decisions are not based on them?

Many NCDs are not issued for new technologies, so they don't require a TA or a MEDCAC. Procedures where medical devices are used (as opposed to drugs) are more subject to NCDs where TAs or MEDCACs are used, since the FDA approval for medical devices assess the safety of the device more than its clinical value, so further clinical evidence is needed to justify coverage, usually based on TAs or MEDCACs.

Do you allow that your opinions appear on my thesis, which will be a publicly available document?

Yes

Do you want to maintain your identity as confidential while allowing your opinions to appear on my thesis?

I agree to disclose my identity

Interview 4. Contractor Medical Director, August 2010

1. According to your experience, are the majority of LCDs for a specific procedure issued before the corresponding NCD? Do NCDs come later after the necessity to have a policy becomes national?

There is not a direct correlation between the time frames for issuing NCDs and issuing LCDs. LCDs are issued to clarify coverage issues that are problematic for providers and that increase the number of claims. These issues are not specific in NCDs.

2. What are the main reasons to issue an LCD in the cases where there is already an NCD?

To describe indications through billing codes not specified in NCDs. Applicable billing codes are not contained in NCDs because CMS doesn't have the economic resources to determine billing codes, which is expensive. That's why it is left to contractor's discretion.

3. According to the Medicare Program Integrity Manual Chapter 13-Local Coverage Determinations (04-25-08) "the DME MACs shall ensure that the adopted LCDs are identical among the DME MACs". Why is consistency between LCDs (by different MACs) required for Durable Medical Equipment and not for other benefit categories?

This is a question for CMS.

4. According to my analysis (based on the CMS Coverage Database), there is consistency between different DME MACs LCDs (all are the same), however, LCD criteria and limitations differ from NCDs in many cases. For other benefit categories LCDs coverage criteria and limitations differ between MACs and between LCDs and NCDs. According to your opinion, what do you think are the causes of these discrepancies if LCDs shouldn't differ from NCDs? (In most of the cases, LCDs narrow the criteria or change limitations without necessarily contradicting the NCD)

5. According to the same manual, "When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors shall allow for individual consideration unless the LCD supports automatic denial for some or all of those other diagnoses/conditions". Most of the discrepancies between NCDs and LCDs that I have detected in my study are

of this type (the NCD didn't exclude coverage for certain diagnosis or conditions while the LCD did). Why do you think this happens?

4 and 5. LCDs don't contradict NCDs, they clarify coverage limitations not specified in NCDs.

6. According to my analysis, some states are more active in issuing LCDs. Which do you think are the main drivers of LCD issuing activity?

The main driver of LCD issuing activity is data analysis of medical necessity criteria based on:

- Quality of care
- History of claims billing errors
- Billing abuse
- Historical problematic areas

An other driver, secondary to data analysis is budget and staff constraints. LCDs and LCD edits are very costly to issue, to maintain and to update. Once you have a new LCD you have to put it in the system. You have to choose very well which procedures merit an LCD. But once you have an LCD in place, it diminish the number of claims that have to be attended individually, decreasing costs for contractors. LCDs diminish claims because the system automatically looks for billing codes applicable to the procedure and automatically denies or authorizes claims based on that.

7. In your opinion, does the current model to issue LCDs taking into account the input from the Carrier Advisory Committee (CAC) from each state works? Does the CAC reflects state-by-state medical practice differences when issuing LCDs? Are these differences desirable? How does the CAC prioritizes for which procedures is an LCD required?

LCDs and CACs reflect differences between states in medical practice. But the priority of LCDs is data analysis. The CAC works only as an advisor to the MCD and the contractor. This specific contractor uses work groups composed of physicians, hospital administrators and advisors on top of the CAC.

8. Why do some contractors issue LCDs only for some states of their jurisdiction and not all?

This doesn't happen any more. When a contractor has LCDs that apply only for some states, usually is because other states were previously managed by a different contractor and they haven't homogenized their policies. But new policies should be issued for all states serviced by the same contractor.

9. *In your opinion, does Medicare Contractor Reform will cause more homogeneous policies between states or more divergent ones?*

Medicare Contractor Reform will produce more consistency between states.

10. *Did you have an experience of issuing an LCD that challenged the standard of practice? Did the LCD have to be changed later?*

Not answered.

11. *According to the Medicare Program Integrity Manual, "Contractors shall implement new Least Costly Alternative (LCA) determinations through an LCD. "Least Costly Alternative" is a national policy provision that shall be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principle to payment for non-DME services as well". Why is the LCA principle mandatory only for DME and not for other benefit categories?*

CMS doesn't allow contractors to use LCA criteria to issue LCDs because recently there was a legal case (Hays vs Sebelius) won by a drug manufacturer over a policy issued under LCA criteria.

12. *According to my analysis, from 193 procedures with NCDs currently in effect (from the following benefit categories: Inpatient Hospital Services, Durable Medical Devices, Diagnostic Laboratory Tests, Physician Services and Diagnostic Tests), only 10 required Technology Assessments and only 12 required a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), leaving the majority of national decisions to the discretion of CMS authorities. According to your opinion, should there be more decisions based on Technology Assessments and MEDCACs? What is the main reason most decisions are not based on them?*

CMS has a limited budget and limited staff, so it is very selective when it uses a TA or a MEDCAC to issue an NCD.

Do you allow that your opinions appear on my thesis, which will be a publicly available document?

Yes

Do you want to maintain your identity as confidential while allowing your opinions to appear on my thesis?

Yes, confidential identity

IX. Statement of conflicts of interests

I don't have any current or potential conflicts of interests between the subject of the present thesis and my professional or academic activities.

X. Glossary of abbreviations

AAMC- Association of American Medical Colleges
AHRQ-Agency of Healthcare Research and Quality
ALJ-Administrative Law Judge
APC-Ambulatory Payment Classification
CAC-Carrier Advisory Committee
CED-Coverage with Evidence Development
CMD-Contractor Medical Director
CMS-Centers for Medicare and Medicaid Services
CPT code-Billing code according to Current Procedural Terminology
DME MAC-Durable Medical Equipment Medicare Administrative Contractor
DME-Durable Medical Equipment
DMERC-Durable Medical Equipment Regional Carrier
ECRI-Emergency Care Research Institute
FAR-Federal Acquisition Regulation
FDA- Food and Drug Administration
FFS-Fee for service
FI-Fiscal Intermediary
GDP-Gross Domestic Product
HCFA- Health Care Financing Administration
HCPCS- Healthcare Common Procedure Coding System
HIPPA- Health Insurance Portability and Accountability Act
HMO-Health Maintenance Organization
ICD-9 code-Billing code according to the International Classification of Diseases, 9th edition
IPPS-Inpatient Prospective Payment System
LCA-Least Costly Alternative
LCD-Local Coverage Determination
LMRP-Local Medical Review Policy
MAC-Medicare Administrative Contractor
MCO-Managed Care Organization
MEDCAC-Medicare Evidence Development & Coverage Advisory Committee
Medicare Contracting Reform- Provisions contained under section 911 of the MMA
MedPAC-Medicare Payment Advisory Commission
MMA- Medicare Prescription Drug, Improvement, and Modernization Act
NCD-National Coverage Determination
NIH-National Institutes of Health
OPPS-Outpatient Prospective Payment System
POS-Point of Service
PPO-Preferred Provider Organization

PSC-Program Safeguard Contractor
QIC-Qualified Independent Contractor
QIO-Quality Improvement Organization
RHHI- Regional Home Health and Hospice Intermediary
TA-Technology Assessment
The Act-Social Security Act

XI. References

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