DHCS RESPONSES TO SENATE HEALTH COMMITTEE QUESTIONS REGARDING PROVIDER MORATORIA

1. What data does DHCS use to establish a moratorium on enrollment of a particular class of providers in Medi-Cal?

DHCS utilizes information gathered from random claim reviews, targeted data reviews and data mining to identify potentially problematic providers. The Medi-Cal Payment Error Study (MPES) is a biennial report that estimates the error rate and the fraud rate in Medi-Cal. The primary objective of the MPES is to identify where the Medi-Cal program is at greatest risk for payment errors. An estimate of the potential dollar loss due to payment errors, including potential loss due to fraud, waste and abuse is computed. The results of the MPES assist in the development of new fraud control strategies such as moratoria, procedure code limitations and temporary suspensions. The DHCS Medical Review Branch conducts audits for recovery of providers identified by the MPES as potentially erroneous billers.

In addition, the DHCS Divisions responsible for the provision of medical services for the Medi-Cal patient population review data to determine if there are sufficient providers to serve the medical needs of this population. DHCS also gathers information about any reported access to care issues through ongoing communication with provider associations, provider organizations, and stakeholders.

2. What data does DHCS use to renew a moratorium on enrollment of a particular class of providers in Medi-Cal?

DHCS currently has three moratoriums in place: 1) clinical laboratories, 2) durable medical equipment, and 3) pharmacies. The DHCS renewal process for each moratorium includes a review every six months to determine and evaluate any possible access to care issues or any recommended amendments. Amendments can include adding new exemptions, modifying or removing current exemptions, or changing the scope of the moratorium in any way. The assessment process utilizes information gathered from random claim reviews, targeted data reviews and data mining to identify potentially problematic providers.

During the renewal process, DHCS analyzes access issues through ongoing communication with provider associations, provider organizations, and stakeholders. For example, the 2009 MPES showed that the overall payment error rate for laboratories was 1.15 percent and in 2011, the rate declined even further to 0.6 percent. Overall, the MPES shows that the laboratory error rate and fraud have been trending downward, which reflects the effectiveness of the moratorium. DHCS sees no need to lift this moratorium as DHCS believes the lab moratorium plays a critical role in keeping

the error rate low and helps minimize cost waste. In addition, internally, various departmental program areas, i.e., Audits and Investigations, Systems of Care and Benefits Division are queried to determine if any access-to-care issues have been identified through any legislative or beneficiary contacts. When access issues have arisen, DHCS has worked with the provider community to address the need, and when possible, established an exemption to ensure access is maintained. The Pharmacy Benefits Division is consulted for input on the Pharmacy Moratorium. DHCS also contacts the Department of Public Health Laboratory Field Services to inquire as to any concerns they may have based on their lab surveys in the State for the lab moratorium.

3. What does DHCS' most recent data show with respect to risk for lab providers relative to other Medi-Cal provider groups? DHCS most recent Payment Error Study (based on 2011 data) found labs had a lower error rate (2.6% for lab vs. 6.1% overall) than most other Medi-Cal providers.

The recent data shows, with respect to billing error rates, lab providers are the second lowest among other Medi-Cal provider groups. This shows the effectiveness of the Clinical Laboratory Moratorium in controlling the population of the providers and allowing DHCS to better monitor payments. This low error rate is a strong indicator that the laboratory moratorium has helped reduce fraud in this service category and DHCS intends to continue in this direction and hold down the fraud potential in this provider type. The moratorium is helping to prevent fraud on the front end and relieves the pressure of conducting "pay and chase" audits on new, inexperienced clinical laboratories.

It's important to note recent findings in the Medicare program. In 2010, Medicare made at least $1.7 billion in questionable Part B payments for clinical laboratory claims that had at least one red flag, such as an ineligible physician identification number or duplicate tests. According to the Office of Inspector General (OIG) Report issued in August 2014, more than 1,000 clinical laboratories had submitted claims to Medicare with five or more measures of questionable billing in 2010.

According to the OIG report, 43 percent of the labs with at least five measures of questionable billing were located in California and Florida, even though only 13 percent of all clinical laboratories are located in those states.

4. Since the original clinical lab moratorium was issued in 2001, the list of exemptions from the moratorium has expanded to 15 separate categories. What criteria does DHCS use to review and determine whether or not to grant an exemption from a moratorium?

There are currently 16 categories of exemptions available for the clinical laboratory moratorium. When a clinical laboratory application is submitted, the applicant identifies the exemption under which they are requesting enrollment. With the exception of those applicants that apply under exemption 11, 14, or 16 of the laboratory moratorium, DHCS's Provider Enrollment Division (PED) reviews the application to determine if the applicant meets the criteria for the exemption. The information submitted in the application package and existing PED enrollment records are used to determine whether the applicant meets the identified exemption.

For applicants requesting enrollment under exemption 11, 14, or 16, the application is reviewed and analyzed by the DHCS Benefits Division medical staff to determine if the applicant meets the criteria. The medical staff review public records of clinical laboratories and DHCS records of enrolled providers to determine if the applicants provide a unique test or if there are other clinical laboratories that conduct the same test. The Benefits Division then notifies PED of their findings. If the applicant meets the criteria, PED continues the review process to verify that the applicant meets all program requirements for enrollment. If the applicant meets all program requirements, they receive notification that they are enrolled. If they do not meet program requirements, they receive notification that their application has been denied.

5. Does DHCS maintain a list of applicants for an exemption from the moratorium? Is there a backlog for these applications? How often and how long does it take for DHCS to review these applications?

DHCS does not maintain an actual list of applicants for an exemption from the moratorium. There is no backlog of these types of applications submitted and under review by DHCS.

During the calendar year 2014, PED received 54 applications from clinical lab providers. Fourteen of these applications did not meet an exemption from the moratorium. Three applications were approved and six applications were denied, and 31applications met an exemption and are in various stages of the full application review process. In summary, 40 out of 54 lab applications (74%) met a moratorium exemption.

During the calendar year 2014, PED received 354 applications from pharmacy providers statewide. Out of 163 pharmacy applications from Los Angeles County (the only moratorium county), five did not meet an exemption, which means 97% of these moratorium county applications met exemptions or were from chain pharmacies or pharmacist-owned pharmacies not affected by the moratorium. In total, statewide, 185 applications were approved, 43 applications were denied, and 121 applications are in various stages of the application review process.

DHCS is compiling similar data regarding the Durable Medical Equipment (DME) moratorium but it will require additional time to complete.

When an application is received, it is first reviewed to determine if the applicant meets the criteria specified in the moratorium exemption being requested. The applicant is notified within 30 days of DHCS's receipt of the application if the applicant does not meet the exemption from the moratorium, as required in the California Welfare and Institutions Code, Section 14043.26(c)(1).

When the provider applicant does meet the claimed exemption, a clinical laboratory application review must be completed within 180 days. Within 180 days, PED must take one of the following statutory actions – deny the application, refer the application or return the application to the provider requesting corrections or additional information. When PED takes one of these actions, the 180 day requirement is satisfied and other timeframes apply according to which action was taken. For instance, if the application is incomplete and is returned to the provider and they return the application to DHCS within 60 days of the notice of deficiency, PED must take another action (deny or refer for onsite visit) within 60 days of receiving the resubmitted application. If the application is complete it is referred to the DHCS Medical Review Branch (MRB) for a mandatory comprehensive onsite review to verify the information provided on the application and the supporting documentation. There is no statutory timeframe for the MRB review to be completed. After the onsite review, MRB reports its findings to PED along with a recommendation to either approve or deny the application. PED then notifies the provider of its decision on the application.

6. The Governor's budget projected that, on average, 70 percent of beneficiaries will be enrolled in managed care in 2013–14 and 73 percent (about 7.5 million Medi–Cal beneficiaries) will be enrolled in managed care in 2014–15. The only individuals remaining in fee-for-services are people pending enrollment in a plan, limited populations with limited scope services (for example, pregnancy only, breast and cervical cancer services) or particular categories of eligibility (for example, former foster youth) or individuals with an exemption from mandatory enrollment in managed care. Given the movement of Medi-Cal beneficiaries into managed care, are Medi-Cal fee-for-service moratorium still needed?

The purpose of establishing moratoriums is to safeguard public funds and maintain the fiscal integrity of the program. Therefore, a moratorium may be extended or repeated when the director determines the action is necessary to continue to safeguard public funds and maintain the fiscal integrity of the program. None of the current enrollment moratoria apply to providers who participate exclusively in the Managed Care side of Medi-Cal.

As stated, more than 70% of Medi-Cal beneficiaries are now enrolled in a Medi-Cal managed care plan network. The movement of Medi-Cal beneficiaries into managed care diminishes the impact of the moratorium on providers; however those new providers for the fee-for-service (FFS) population are impacted. DHCS has not seen a

dramatic decrease in fraud in FFS Medi-Cal since the expansion to managed care. Maintaining all of the current moratoria ensures that DHCS keeps a proven tool to protect and maintain the progress made in its effort to curtail fraudulent providers in FFS Medi-Cal.

7. The policy proposal by SB 1212 (Walters) from 2014 was that if a clinical lab passes the scrutiny of a Medi-Cal managed care plan and is able to bill the Medi-Cal managed care plan, that clinical lab would be able to bill fee-for-service Medi-Cal. Does DHCS have a view on this policy proposal as providing acceptable criteria for an exemption from a provider moratorium?

DHCS notes that the screening tools are not equal for both managed care providers and FFS providers. Managed care plans are not required to conduct the same levels of provider screening required by the Patient Protection and Affordable Care Act (ACA) because the managed care plans assume all risk associated with the qualifications of the lab providers in the plan and the claims that are submitted by those providers. In FFS, DHCS assumes all risk associated with the qualifications of and claims payments to the providers participating in FFS Medi-Cal.

Medi-Cal managed care plans, and subsequently, clinical laboratories that have an existing contractual relationship with these plans or their subcontractors, are reimbursed through capitated (set amount per beneficiary) contracts. These contracts include beginning and end dates and terms for revocation of the contracts. For FFS Medi-Cal to allow lab providers to be exempt from the moratorium based on the existence of a current contract with a Medi-Cal managed care plan that may end or be revoked would be basing a moratorium exemption on a condition that is not permanent and is not easily verifiable by FFS Medi-Cal.

8. If a provider contracts with a Medi-Cal managed care plan as indicating a low risk of fraud for that type of provider (as proposed by SB 1212), should the exemption in SB 1212 also apply to other providers currently subject to a moratorium?

The fact that a laboratory provider, or any type of provider, has a contract with a Medi-Cal managed care plan is not an indicator that the provider is a low risk of fraud. Risk levels have been established for specific provider types in Federal Medicaid Regulations based on the Centers for Medicare and Medicaid Services' (CMS) assessment of fraud, waste and abuse risk of the provider or supplier category.

The ACA designates independent clinical laboratories as "moderate risk" and the State Medicaid agency must screen these types of providers at this risk level. Because the laboratories are designated as "moderate risk", their screenings require an onsite inspection by the State Medicaid Agency. The CMS designation of independent clinical

laboratories as “moderate risk” indicates that there is concern with this provider type even at the federal level.

Durable Medical Equipment (DME) providers are subject to a regional moratorium and the ACA designates the currently-enrolled DME providers to be screened as “moderate risk” and any newly-enrolling DME providers be screened as “high risk”, which includes fingerprint submission for criminal background checks.

Non-chain, Non-pharmacist owned pharmacies in Los Angeles County are also subject to a moratorium. This provider type is designated as “limited risk” under Federal regulations, but DHCS conducts onsite visits as part of the screening for all pharmacy applicants in Los Angeles County and all “closed door” pharmacies.

9. Are there other credentialing or bonding criteria that could address DHCS’ concern about fraud resulting from particular groups of fee-for-service Medi-Cal providers?

At this time there is no other credentialing or bonding criteria that would address or allay DHCS’s fraud concerns from particular groups of providers. Because fraud continues to be a significant national concern, Federal regulations under the ACA have required DHCS to implement additional anti-fraud tools for screening of high risk providers. Also, with the implementation of the ACA, CMS for the first time established moratoriums as an anti-fraud tool in the Medicare program. Moratoria have been a very effective strategy for addressing fraud in service categories that have historically had high levels of fraud.

10. Does DHCS track Medi-Cal fee-for-service lab expenditures that go to out-of-state companies? One of the issues raised during the discussion of SB 1212 was the moratorium was resulting in lab work being done out-of-state.

DHCS can track reimbursement to out-of-state laboratory providers as needed. Of the 478 clinical laboratory providers enrolled in FFS Medi-Cal, only 12 are located out of state. In addition, the percentage of monies paid to out-of-state laboratories is relatively small.

The FFS Medi-Cal program paid the following amounts to out-of-state laboratory providers in the five year period of 2010 – 2014. (Amounts rounded off to ten thousands)

- 2010 - $4,680,000
- 2011 - $5,760,000
- 2012 - $4,140,000
- 2013 - $5,510,000

- 2014 - $3,950,000

11. One of the provisions of the current clinical lab moratorium is a prohibition on labs that became providers after March 2001 from expanding their scope of service? What is the rationale for this restriction?

Placing restrictions on the expansion of lab services is another means of limiting potentially fraudulent lab claims. By restricting the expansion of allowable claim codes, DHCS can control the size of lab providers for oversight as well as prevent fraud. Given the movement of beneficiaries into managed care, there has not been a demonstrated need for the FFS Medi-Cal program to have more labs. DHCS believes the moratorium has protected the Medi-Cal program from illegitimate laboratories.

DHCS received a complaint that laboratories were overcharging the Medi-Cal program by not billing the lowest available for laboratory services as required by law. Some labs were billing other payees a lower rate that the Medi-Cal program was billed in exchange for exclusive referral arrangements. The claims system would be blind to this practice. In response, MRB conducted field audits of all laboratory providers receiving in excess of $500,000 per year. Three hundred labs that earned less were directed to conduct "self-audits". Twenty six field audits identified $5.1 million in overpayments. Eight labs were indicted by the Department of Justice for participation in this scheme. These oversight activities lead to changes in the pricing structure and result in savings of millions of dollars to the Medi-Cal program. This indicates the necessity of maintaining the laboratory moratorium.

12. Does the current moratorium prevent new clinical labs, and clinical labs that became Medi-Cal providers after March 2001, from offering potentially new or higher quality services to Medi-Cal beneficiaries?

    No. Exemptions 14 and 16 in the current moratorium address this issue. In addition, Exemption 13 allows for new business activities, categories of service or billing codes for clinical laboratories that meet the criteria for this exemption.

13. Does DHCS have an estimate of savings attributable to the moratorium (e.g., is there a dollar amount of how much fraud cost and was averted as a result of the moratorium)? Are we losing more health saving opportunities than we are saving in fraud prevention policies?

DHCS does not have an estimate of the cost savings achieved by the moratoria. However, DHCS does track beneficiary access to care to ensure that the moratoria are not preventing beneficiaries from receiving necessary services.

14. Has the moratorium had the unintended consequence of preventing lab tests that might be more effective or cost less from providing services in the Medi-Cal fee for

service program (for example, is the state losing Medi-Cal savings opportunities than it is saving in fraud prevention policies)?

DHCS has no definitive data to show that the state is losing Medi-Cal savings. Whether the moratorium consequently prevents labs from offering services at lower competitive prices is not verifiable for a number of reasons. Lab services cannot be initiated without an order from a physician. As lab services must first be ordered by a physician, there is no way to know which lab a physician may choose for a patient. Choices are based on the physician's best interest in the care of their patients or a location convenient for the patient. A physician may choose to send their patient to a lab that has proven to be reliable in terms of lab results performance. A physician would not be aware of which labs offer competitive pricing. An enrollment moratorium in place has no direct or measurable effect on which labs receive orders for tests and what they charge for those tests.

In August 2014, DHCS addressed an issue related to beneficiary access to medically necessary testing services that were not covered Medi-Cal benefits. Although a particular test may not be a covered benefit, the test can be approved for the beneficiary through the treatment authorization request process. The lab moratorium prevented access to such tests not currently offered by other Medi-Cal providers. A clinical lab that performs those particular tests was unable to enroll because the tests were not considered covered benefits. In this instance, DHCS modified the laboratory moratorium exemption criteria and added exemption 16, which allowed for any CLIA approved clinical laboratory that performs a test that no other Medi-Cal enrolled laboratory offers, to be enrolled and then reimbursed only for that test or examination as approved by DHCS.

The California Children's Hospital Association (CCHA) contacted DHCS to express concerns that the moratorium may be preventing access to genetic testing for children in the CCS program. CCHA expressed concerns that new labs can't become Medi-Cal providers unless they offer a unique test and they note some children's hospitals don't know where to send their genetic tests because they don't know whether a lab is approved to bill Medi-Cal for a given test. In addition to creating exemption 16, DHCS has been working with CCHA to assist in identifying eligible providers that provide unique genetic tests.