



Mr. John Medoza
Acting Chief of Fee for Service and Rates Development Division
Post Office Box 997413 M.S. 4612
Sacramento, CA 95899 – 7413
John.mendoza@dhcs.ca.gov

Re: Data Elements and format for rate submission information for Clinical Laboratory Services: AB 1494

Dear Mr. Mendoza,

Thank you for the opportunity to provide comments regarding the data elements for the new rate setting methodology contained in AB 1494. Genomic Health Incorporated is based in Redwood City, CA and is committed to improving the quality of cancer treatment decisions through the research, development and commercialization of genomic-based clinical laboratory services.

As only a small fraction of cancer patients have tumors that will favorably respond to expensive chemotherapy, the need for such genomic-based clinical laboratory services for cancer patients is significant. The level of resources and time necessary to develop such services that can provide cancer patients and their physicians' accurate and reliable information specific to their tumor is significant as well. Currently these are not services that are broadly replicable and replaceable with generic alternatives.

One of our services, the *Oncotype DX™* Breast Cancer Assay is used in clinical practice to quantify the likelihood of breast cancer recurrence for an individual patient and is currently considered medically necessary for Medi-CAL beneficiaries. As this service is ordered by physicians for the majority of early stage breast cancer patients, is included in guidelines developed by the National Comprehensive Cancer Network and the American Society of Clinical Oncology, this service is viewed as a standard of care for early stage breast cancer patients.

Genomic Health's support for Medi-Cal and all Medicaid Patients

Genomic Health is considered a network provider to a vast majority of private insurers, Medicare, and within the Medi-CAL Program. To date, our Medicare, VA, DOD, Tricare and Medicaid rates are all far below our average reimbursement and claims payment rates across payors. The rate of reimbursement developed within Medicaid programs is considerably below what private insurers have recognized as the value of the service.

In 2011, nearly 300 Medi-Cal patients were tested with the Oncotype Dx Breast cancer assay. Estimated savings stated by both Dr. Francis Collins of NCI and a recent article published by Dr. Lou Hochheiser et al from Humana documented substantial savings to their programs¹ and to all payors that have adopted coverage policies. Using the same published budget impact model for Medi-Cal as was used in these references above, the California Medicaid program has saved more than \$300,000 in unnecessary chemotherapy costs for 2011.

Proposed Data Reporting

Option 1: For single source labs, whereby contracting does not occur directly with physicians or hospitals and only occurs directly with the payors, we propose an exemption from the rate reporting system. We can report a yearly average reimbursement rate to show compliance and commitment towards best rate reimbursement for Medicaid programs which can be compared to the existing payment set. The existing 80% of Medicare payment ensures that Medi-Cal is receiving best pricing relative to Medicare and private payor markets as our Medicare rate is substantially below that of commercial insurers.

Option 2:

Genomic Health would propose a submission method similar to that of the pharmaceutical industry to CMS when certifying ASP (Average Sales Price) dollars. We would be happy to provide DHCS with our Average Commercial Contracted Payment rate, as well as our average rate for federal government programs combined. These would be two rates easily comparable when considering multiple lab submissions and would also ensure that MediCal rates are consistent with government pricing and best rate practices compared to commercial payors.

Example:

- Average Commercial Contracted payment (or claims payment rate)
- Medicare reimbursement rate
- Average Government claims payment rate (Medicare, VA, DOD, Medicaid rates all included)



Option 3:

Exemption for low volume laboratories.

Example:

A laboratory that bills less than 1000 tests/year would not be subject to the new rate-setting methodology in AB 1494.

Thank you for the opportunity to share an overview of a single source laboratory's services to Medi-Cal along with our recommendation for fulfilling the requirements outlined in AB 1494 with regards to reimbursement review and rate setting policy.

We would be happy to meet with you or your staff at DHCS's rate development division to walk through our proposals.

Sincerely,

Donna Polizio

A handwritten signature in black ink that reads 'Donna Polizio'.

Sr. Genomic National Account Manager-Government

Genomic Health | 301 Penobscot Drive | Redwood City, CA 94063 |

dpolizio@genomichealth.com

ⁱ Hornberger, J, Chien R, Krebs K, Hochheiser, L. *Am J Manag Care.* 2011;17(5 Spec No.):e194-e202)