

## CMS Proposes New Medicare Reporting and Payment System for Laboratories

***Proposed rule will create significant, retroactive reporting requirements for private payor payment rates to clinical laboratories.***

Many clinical laboratories will need to expend significant resources to track, collect and report private payor payment rates for certain of their tests, retroactively from July 1, 2015, through December 31, 2015, in order to comply with the Centers for Medicare & Medicaid Services (CMS)'s [proposed rule published on October 1, 2015, in the Federal Register](#) (Proposed Rule). The Proposed Rule outlines CMS's proposed approach to implementing Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA). PAMA established a new payment system for clinical diagnostic laboratory tests (CDLTs) and certain molecular diagnostic tests that meet the definition of advanced diagnostic laboratory tests (ADLTs). Under the new Medicare payment system, Medicare payments for CDLTs and ADLTs will be tied to private payor payment rates, such as commercial health plans and Medicare and Medicaid managed care plans (with certain exceptions for new tests).

### The Proposed Rule

The Proposed Rule, if implemented as proposed, will require "applicable laboratories" (as defined in the Proposed Rule) that bill Medicare for CDLTs and ADLTs to collect private payor pricing data for an initial data collection period beginning retroactively on July 1, 2015, and ending December 31, 2015. Applicable laboratories will be required to report pricing data by March 31, 2016, imposing a significant burden on laboratories to implement systems to collect and track pricing data. The laboratory industry likely will press CMS to delay the implementation of the collection and reporting requirements until a final regulation is published.

Effective January 1, 2017, CMS will establish new payment rates for CDLTs (which will be in effect for three years) and ADLTs (which will be in effect for one year) using the weighted median of the private payor rates reported by applicable laboratories for each test. Special reporting and payment rules apply to new CDLTs and ADLTs. After the initial data collection period, laboratories performing CDLTs will be required to collect, track and report data every three years for those tests. Laboratories performing ADLTs must collect, track and report data every year, and the Medicare payment rate for those tests will be established annually.

"New" ADLTs under the Proposed Rule are ADLTs for which payment was not made under the Clinical Laboratory Fee Schedule (CLFS) prior to January 1, 2017. For an initial period of three full quarters following the date a new ADLT is made available, CMS will establish a Medicare payment rate based on either the test's actual list charge or the publicly available rate on the first day that the test is available for purchase by a private payor. The rate is subject to potential recoupment if the new ADLT's initial three-

quarter period rate is more than 130% of the Medicare payment rate determined using private payor data available after the initial period. Payment for new CDLTs that are not ADLTs will be determined using crosswalking or gapfilling methodologies until private payor data is available.

Laboratories are facing a new pricing regime that will require them to expend extensive legal and financial resources to comply with the new legal requirements and accurately track pricing information and price concessions similar to pharmaceutical manufacturers. Laboratories may be subject to civil monetary penalties (CMPs) in an amount up to US\$10,000 per day for each failure to report or for each misrepresentation or omission, which is consistent with the level of CMPs imposed on pharmaceutical manufacturers for average sales price (ASP) reporting issues. In the absence of sufficient guidance from CMS, laboratories may seek to develop reasonable assumption policies and documentation to support their good faith effort to comply with the complex regulations.

Comments on the Proposed Rule are due no later than 5 p.m. Eastern Standard Time on November 24, 2015.

## Who is Required to Report?

CMS proposed that applicable laboratories that meet a four-part test will be required to report private payor pricing data. An “applicable laboratory” is an entity for which all of the following apply:

- Reports tax-related information under a Taxpayer Identification Number with which all of its National Provider Identifiers (NPIs) are associated;
- Is a laboratory (or has at least one component that is a laboratory), as defined by the Clinical Laboratory Improvement Amendments of 1988 (CLIA);<sup>1</sup>
- Receives, collectively with all of its associated NPIs, 50% or more of its total Medicare revenue (*i.e.*, payments from Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D and any associated Medicare beneficiary deductible or coinsurance amounts) from laboratory tests paid under the CLFS or the Physician Fee Schedule during the data collection period; and
- Receives, collectively with all of its associated NPIs, at least US\$50,000 in revenue from tests reimbursed under the CLFS during the data collection period.

CMS estimates that approximately 94% of physician office laboratories and 52% of independent laboratories will be excluded from the reporting requirements. Many hospital-based laboratories may be excluded from the reporting requirement because those hospital entities, under their collected NPIs, are unlikely to receive more than 50% of their total Medicare revenue from laboratory tests. Many small, physician-based laboratories may be excluded because they generate less than US\$50,000 from tests paid under the CLFS.

The proposed definition of “applicable laboratory” presents compliance challenges for laboratories. Because the applicable laboratory test is dependent, in part, on Medicare revenue and percentages calculated during the data collection period, a laboratory may not know at the outset of that time period whether it will ultimately be subject to the reporting requirements. Laboratories may face uncertainty on the important decision of whether to implement systems and expend resources to track and collect pricing data during the collection period.. Furthermore, including Medicare Advantage payments in the definition of Medicare revenue may generate difficulties for a laboratory to determine accurately whether it meets

the 50% Medicare revenue test because a laboratory may not be able to distinguish Medicare Advantage payments from other private payor payments.

## What are ADLTs?

Certain molecular tests that qualify as ADLTs will be subject to annual price collection and reporting requirements, and “new” ADLTs (ADLTs that were not paid on the CLFS prior to January 1, 2017) will be subject to special pricing and reporting requirements for an initial period after they are launched. ADLTs are a subset of CDLTs covered under Medicare Part B that are marketed and performed by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner), and are either: (1) cleared or approved by the Food and Drug Administration (FDA); or (2) meet the criteria established for non-FDA approved or cleared tests.

The criteria for non-FDA cleared or approved tests include three required components: (1) the test is a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA); (2) when combined with an empirically derived algorithm, the test yields a result that predicts the probability a specific individual patient will develop a certain condition or respond to a particular therapy; and (3) the test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. The test may include other assays. Unique codes will be assigned to each FDA-approved or cleared test if a code does not already exist, and CMS will assign Healthcare Common Procedure Coding System Code (HCPCS) codes for new ADLTs; however, CMS did not indicate whether different codes will be issued for each approved or cleared test using the same analyte or for each new ADLT.

In order to obtain ADLT status for a test, laboratories will be required to submit documentation to support their application. While laboratories will be required to produce their algorithms and other sensitive information about their technologies to CMS, CMS has not assured laboratories that their information will be protected from public disclosure. CMS does not expect to make the information in an ADLT application available to the public, but the information will not be explicitly protected from disclosure under the confidentiality provisions of the statute, nor will the information be explicitly protected from disclosure in response to Freedom of Information Act (FOIA) requests.<sup>2</sup>

CMS has proposed a narrow view of what constitutes a single laboratory — the holder of a single CLIA certificate — and awards the special payment status to the one laboratory that developed, markets, performs and sells the test. This proposed approach will prevent companies that develop new tests from receiving ADLT status for all of their affiliated CLIA-certified labs that perform the test. Developers of ADLTs may need to structure their development, marketing and performance functions carefully to attain ADLT status for their tests. Additionally, labs will need to consider carefully whether they should pursue an FDA pathway or a non-FDA pathway for obtaining ADLT status, including weighing the disadvantages and advantages of each pathway. For example, CMS proposed a high bar for ADLTs pursuing the non-FDA pathway by requiring that the test provide new clinical information that cannot be obtained from any other existing test or combination of tests on the market, not just that the test be superior to existing technologies.

A premium likely will be placed on being the first developed test because CMS does not appear to intend to grant ADLT status to follow-on technologies under the non-FDA pathway. Competitor products or follow-on technologies or improvements that fail to satisfy the new clinical information threshold, which were, for example, more reliable or less expensive, may not qualify as ADLTs under the non-FDA pathway.

## What Information Must Laboratories Report?

If the Proposed Rule is implemented as proposed, applicable laboratories will be required to report applicable information every three years for CDLTs and every year for ADLTs that are not new tests. For each test, the applicable information for each data collection period includes:

- The specific HCPCS code associated with each laboratory test;
- The rate each private payor (e.g., health insurance issuers,<sup>3</sup> group health plans, Medicare Advantage plans and Medicaid managed care organizations) paid, reflecting any price concessions plus any patient deductibles and coinsurance amounts, but excluding any payments made on a capitated basis or similar payments; and
- The volume of the tests performed at each payor rate during the data collection period.

Further, the President, Chief Executive Officer or Chief Financial Officer of the applicable laboratory (or an individual with appropriate delegated authority) must sign a certification statement that the information provided is accurate, complete and truthful, and meets all the reporting requirements.

The Proposed Rule does not provide guidance on a number of data reporting issues, which may cause difficulties for laboratories to report accurately their pricing data. Unresolved questions include how laboratories should allocate out-of-network payments or allocate payment adjustments (for example, on appeal) that occur outside of the collection period but for services initially performed and paid during the collection period. CMS has proposed to apply the price concession definition applicable to ASP reporting for pharmaceutical products (that includes discounts, rebates and coupons as well as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement and chargebacks). Laboratories will need to develop financial management systems, to expend significant resources to comply and to document their good faith effort to comply with the complex price reporting requirements, especially in the absence of clear guidance.

## When Must Laboratories Collect and Report Data?

The initial data collection period proposed by CMS is the six-month period beginning July 1, 2015, and ending December 31, 2015, requiring laboratories to collect and track pricing data for claims paid prior to publication of the Proposed Rule or finalization of the reporting requirements. As proposed, laboratories will be required to report applicable information to CMS by March 31, 2016. Requiring laboratories to collect and report data in the absence of any final guidance may result in laboratories reporting unreliable data and, therefore, inaccurate payment rates being set for 2017 for ADLTs, and for 2017-2019 for CDLTs. The lack of final guidance also imposes a significant burden on clinical laboratories over the next few months to implement the financial management and compliance systems to determine whether they are applicable laboratories and to report the required pricing data.

After the initial data collection period, CDLT laboratories will be required to collect, track and report pricing data for 12-month collection periods every three years and to report the pricing data within three months of the end of the applicable data collection period. After the initial data collection period, the next CDLT collection period will be January 1, 2018, through December 31, 2018, requiring laboratories to report applicable information by March 31, 2019. ADLT laboratories are subject to annual collection and reporting requirements. After the initial data collection period, ADLT laboratories will be required to collect and track data during a collection period beginning January 1, 2016, and ending December 31, 2016, and to report applicable information by March 31, 2017.

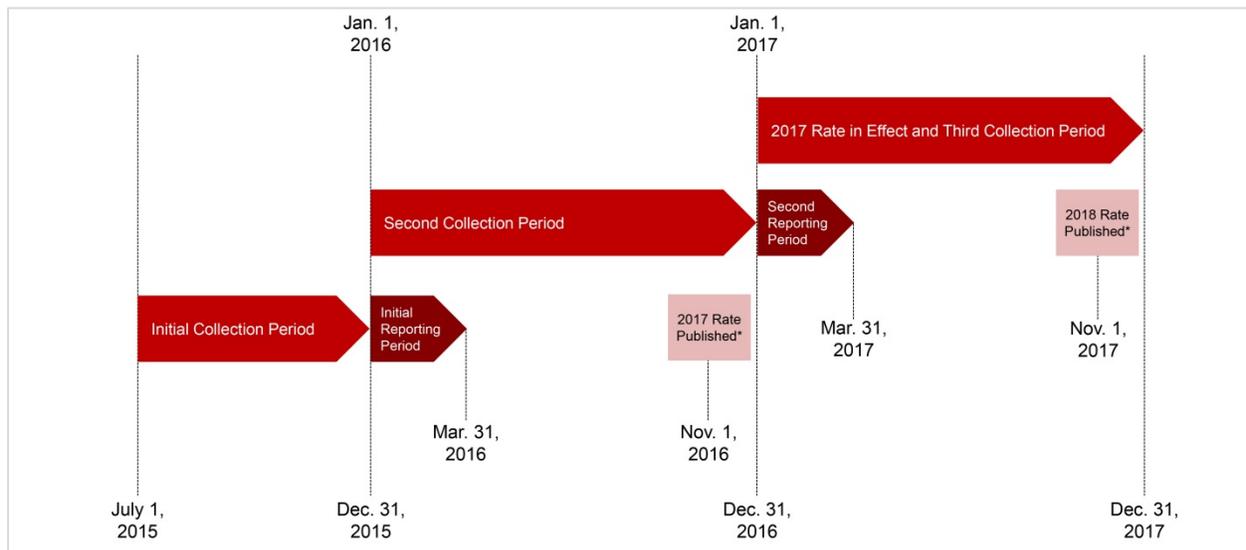
## How Will CMS Establish the 2017 Payment Rates?

As illustrated in the three tables below, CMS proposed to establish payment rates for CDLTs and ADLTs effective January 1, 2017, based on the price reporting data reported for the six-month period beginning July 1, 2015, and ending December 31, 2015. CMS proposed publishing final payment rates at least 60 days prior to their implementation date, which would be approximately November 1, 2016. However, CMS did not propose a notice and comment period for proposed payment rates similar to other Medicare payment systems. The Medicare payment amount will be equal to the weighted median price for the test, determined by data laboratories submit for the most recent data collection period. CMS will calculate the weighted median of a test by first arraying the distribution of the private payor rates reported during the collection period from the lowest rate to the highest rate, and then selecting the middle rate of this array as the weighted median value. This value will not be subject to any additional adjustment (e.g., geographic adjustment, budget neutrality adjustment, inflation update, annual update, etc.); however, the value will be subject to any reduction resulting from the sequester.

If the new payment calculation methodology will result in a significantly reduced payment for a test, CMS proposes to phase-in the reduction over a series of years. Any payment reduction for CDLTs or ADLTs that are not new tests is proposed to be limited to 10% of the preceding year's payment for a test in years 2017 through 2019, and limited to 15% of the preceding year's payment for a test in years 2020 through 2022. This provision will help mitigate any significant reductions in payments after the implementation of the new payment system; however, this provision also indicates that some CDLTs may experience dramatic shifts in payment amounts. CMS estimates that Medicare spending on CLFS services will decrease by US\$360 million in 2017, a reduction of 4.5%.

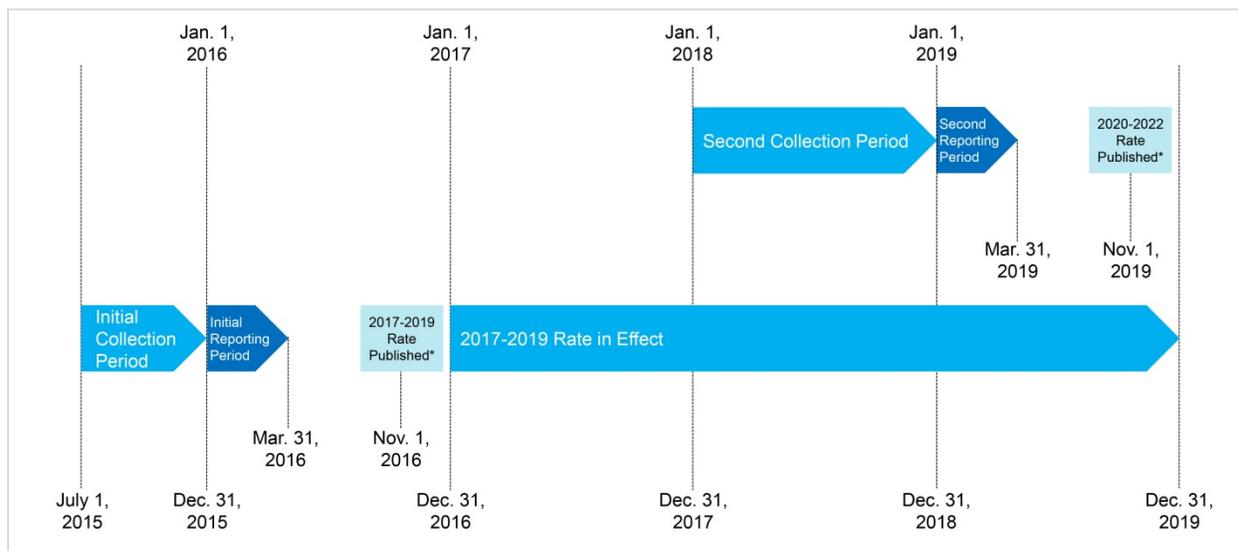
When no private payor payment data is available, CMS proposed to pay for tests using either crosswalking or gapfilling methodologies.

**Table 1: ADLT Timeline**



*\*CMS proposed that it will publish the new Medicare rates 60 days in advance of the implementation date.*

**Table 2: CDLT Timeline**



\*CMS proposed that it will publish the new Medicare rates 60 days in advance of the implementation date.

### How Will CMS establish Payment Rates for New CDLTs?

CMS proposed to continue its current crosswalking and gapfilling processes to establish payment for CDLTs that are assigned new or substantially revised HCPCS codes. Until private payor data is available, CMS proposed to use its current crosswalking process when a new CDLT is comparable to an existing test, multiple existing tests or a portion of an existing test. When no existing test is comparable to a new CDLT, CMS proposed to use its gapfilling process (*i.e.*, to “fill the gap” where no crosswalk is available).

### How Will CMS establish Payment Rates for New ADLTs?

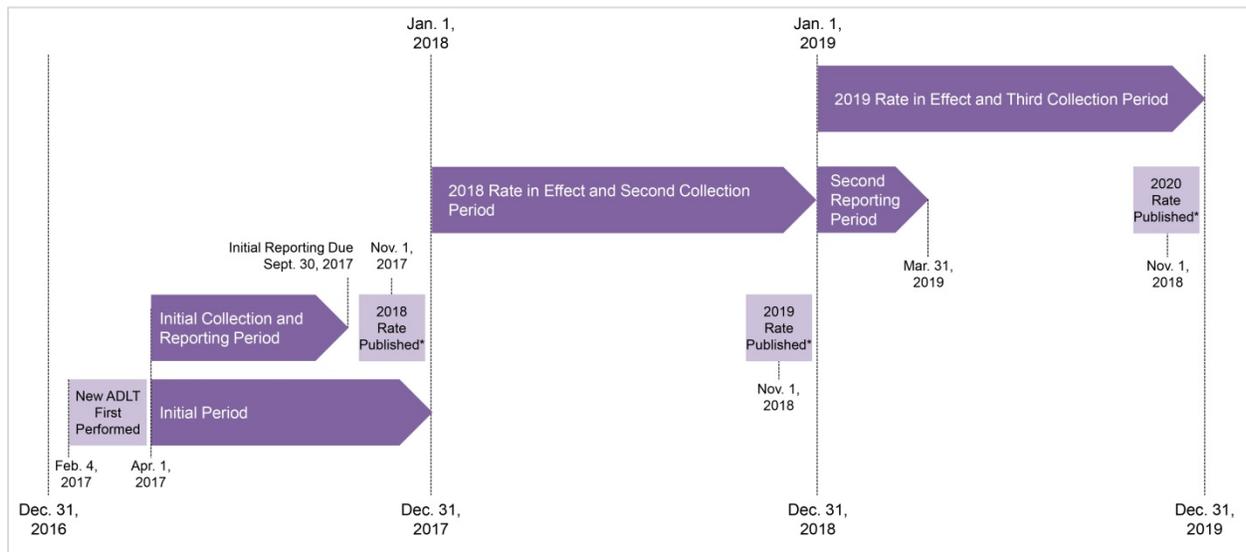
As proposed, new ADLTs are tests for which payment has not been made under the CLFS prior to January 1, 2017. Under PAMA, new ADLTs are tests that were reimbursed after April 1, 2014. CMS states that PAMA authorized the agency to adopt methodologies for pricing, coding and coverage in effect before January 1, 2017. Tests reimbursed after April 1, 2014, but before January 1, 2017, will not be eligible under the new ADLT payment rules that allow an ADLT to be reimbursed based on its list price for three quarters, as described below in more detail.

CMS proposed that the initial payment amounts for new ADLTs will be based on an initial period of three full calendar quarters, which will start on the first day of the first full calendar quarter following the first day on which a new ADLT becomes available. The first day a test is available means the date a test can be obtained by a patient who is covered by a private payor or the date the test can be marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date. Developers of new ADLTs should, therefore, plan for up to a full calendar year for the initial period. During the period between when the ADLT is first performed and the first day of the initial period, the Medicare Administrative Contractor (MAC) will work with the laboratory to develop a payment rate for the new ADLT. During the initial period, the ADLT will be paid at the actual list charge or the publicly available rate (*i.e.*, the lowest amount charged that is readily accessible on the laboratory’s website, price listing or test registry) on the first day the test is available for a private payor to purchase.

Laboratories must report private payor data not later than the last day of the second full quarter after the test becomes available. After the initial period, the payment rate will be determined using the payment methodology described above in the section “**How Will CMS Establish 2017 Payment Rates?**”

Laboratories that establish a list price for the initial period that does not reasonably reflect the expected private payor rate for the test could face recoupment. If the Medicare payment amount during the new ADLT initial period (*i.e.*, actual list charge) is more than 130% of the Medicare payment amount determined using the weighted median of private payor rates that is applicable after the initial period, CMS will recoup the difference between the Medicare payment amounts during the initial period and the Medicare payment amount based on the weighted median of private payor rates reported by the ADLT laboratory.

**Table 3: New ADLT Timeline**



\*CMS proposed that it will publish the new Medicare rates 60 days in advance of the implementation date.

## Conclusion: Prepare for the New Private Payor Collection and Reporting Requirements

Laboratories are facing a new pricing and reporting regime and potential CMPs of US\$10,000 per day for each failure to report or for each misrepresentation or omission, similar to the requirements and potential penalties imposed on pharmaceutical manufacturers for ASP reporting. In light of the significant potential penalties, laboratories may be required to expend significant resources to assure compliance with the new requirements, such as developing financial management systems to collect and track data, establishing a cross-functional team of contracting, legal and finance personnel to develop policies and to monitor reporting, and creating pricing policies and reasonable assumption documentation to address issues in the absence of clear guidance from CMS to demonstrate the company’s good faith effort to comply with the requirements. Laboratories should continue to monitor developments, such as sub-regulatory guidance from CMS on the ADLT application process and other reporting details, while preparing for implementation.

If you have questions about this *Client Alert*, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

**Stuart Kurlander**

stuart.kurlander@lw.com  
+1.202.637.2169  
Washington, D.C.

**Nicole Liffrig Molife**

nicole.liffrig@lw.com  
+1.202.637.2121  
Washington, D.C.

**Michael Dreyfuss**

michael.dreyfuss@lw.com  
+1.202.637.2271  
Washington, D.C.

**Eric Greig**

eric.greig@lw.com  
+1.713.546.7456  
Houston

**Robert Canning**

robert.canning@lw.com  
+1.202.637.3388  
Washington, D.C.

**Steven Schnelle\***

steven.schnelle@lw.com  
+1.202.637.1091  
Washington, D.C.

*\*Qualified to practice in Massachusetts. Not yet qualified in Washington, D.C.*

---

*Client Alert* is published by Latham & Watkins as a news reporting service to clients and other friends. The information contained in this publication should not be construed as legal advice. Should further analysis or explanation of the subject matter be required, please contact the lawyer with whom you normally consult. The invitation to contact is not a solicitation for legal work under the laws of any jurisdiction in which Latham lawyers are not authorized to practice. A complete list of Latham's *Client Alerts* can be found at [www.lw.com](http://www.lw.com). If you wish to update your contact details or customize the information you receive from Latham & Watkins, visit <http://events.lw.com/reaction/subscriptionpage.html> to subscribe to the firm's global client mailings program.

**Endnotes**

---

<sup>1</sup> The CLIA defines a laboratory as a facility for the biological, microbiological, immunohematological, hematological, biophysical, cytological, pathological, or other examination of material derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence of absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories. See 42 C.F.R. § 493.2 (2015).



---

<sup>2</sup> To obtain protection under FOIA, the entity may show that the requested information or algorithm meets a FOIA exemption, such as the exemption for trade secrets and commercial or financial information obtained from a person that is privileged or confidential (e.g., the applicant will need to demonstrate that substantial competitive harm will occur if the information is disclosed).

<sup>3</sup> A health insurance issuer is defined in section 2791(b)(2) of the Public Health Service Act as an insurance company, insurance service, or insurance organization (including health maintenance organizations), which is licensed to engage in the business of insurance in a state and which is subject to state law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974).