

Fang He
Darryl Creel
Leah Sussman
Lindzee Smith
Phillip Kott
Tom Hoerger
John Kautter
Greg Pope
RTI International

•

MedPAC
425 I Street, NW
Suite 701
Washington, DC 20001
(202) 220-3700
www.medpac.gov

•

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Evaluating the CMS Methodology for Setting Private Payer Based Rates for Clinical Lab Tests: Final Report

*A report by staff from RTI International for the
Medicare Payment Advisory Commission*

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Evaluating the CMS Methodology for Setting Private Payer Based Payment Rates for Clinical Lab Tests Final Report

Prepared for

Brian O'Donnell

Carolyn San Soucie

Medicare Payment Advisory Commission

425 I Street, N.W.

Suite 701

Washington, DC, 20001

Prepared by

Fang He

Darryl Creel

Leah Sussman

Lindzee Smith

Phillip Kott

Tom Hoerger

John Kautter

Greg Pope

RTI International

3040 E. Cornwallis Road

Research Triangle Park, NC 27709

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EXECUTIVE SUMMARY

Clinical laboratory tests provide patients and providers with information that assists with the diagnosis, prevention, and treatment of disease. In 2018, clinical lab testing accounted for \$7.6 billion of Medicare spending, with reimbursement rates established by the Clinical Laboratory Fee Schedule (CLFS).¹ The CLFS ties Medicare reimbursement rates to Healthcare Common Procedure Coding System (HCPCS) codes, more than 1,330 unique codes in 2018. Medicare uses these rates to pay independent, hospital, physician office, and other labs (CMS, 2020).

In 2018, the Centers for Medicare & Medicaid Services (CMS) started a new payment system to set Medicare lab payment rates based on private payer rates. Specifically, CMS paid labs the median, weighted by testing volume, of private payer rates, as reported by applicable labs.² Following the first round of calculations of Medicare payment rates under this new payment system, clinical lab industry stakeholders asserted that CMS was underpaying for lab services because of the preponderant sample of large, independent labs in the payment calculation. Ahead of the second round of reporting, Congress directed the Medicare Payment Advisory Commission (MedPAC) to examine potential alternate methods to CMS's initial methodology used to set 2018 payment rates. The purpose of this report is to examine options to collect data that would result in a representative and statistically valid sample of the various market segments for each CLFS HCPCS code with the least burden on labs, with a focus on reducing burden for smaller labs for whom reporting would be most difficult.

We used 2018 Medicare claims data to construct separate sampling frames for independent, hospital, and physician office labs so that the resulting samples are representative of each type. Each sampling frame is a list of labs: one of all independent labs, one of all hospital labs, and one of all physician office labs. Together, these three lab types account for nearly 100% of Medicare payments and volume for CLFS lab tests. Constructing separate sampling frames for each lab type helps to address the main criticism of CMS's approach in the first round of reporting private lab payment rates, which was that the labs reporting private payer rates were disproportionately independent labs.

¹ This \$7.6 billion is based on our analysis of 2018 Medicare claims data and includes testing billed by hospital labs for patients in the inpatient and outpatient settings that were paid through the CLFS.

² CMS is gradually phasing in reductions to Medicare payment rates. From 2018 through 2020, CMS limited reductions to payment rates annually at 10 percent, as outlined in the Protecting Access to Medicare Act of 2014 (GAO, 2018). CMS is limiting reductions to 0% in 2021 and 15% from 2022 through 2024 (CMS.gov, 2021).

We used two sampling methods: stratified sampling and Maximal Brewer Selection (MBS). Stratified sampling is a commonly used sampling method that divides the sampling frames into mutually exclusive and exhaustive subpopulations, known as sampling strata. One then samples independently from the sampling strata. For our analysis, the sampling strata are the HCPCS codes and the sampling units are the labs. Typically, in stratified sampling, sampling units are unique to each sampling strata. For example, if we are sampling people by age and sex categories, each person (the sampling unit) is only in one age-sex category (sampling strata). However, in sampling labs, most labs (the sampling unit) bill for multiple HCPCS codes (sampling strata). This presents challenges to our sampling process. One of the main challenges is that labs are only allowed to be in one HCPCS code stratum for sample selection (although once sampling is completed, a lab can report information on more than the one code for which they are selected). Because of this, the challenge is determining in which HCPCS code stratum to place a lab for sampling.

Our second sampling method, MBS, does not require explicit stratification by HCPCS code. Previously, MBS has been used to collect data for commodities produced by farms, in which farms can produce different sets of commodities. Since this previous application of MBS is analogous to collecting data for HCPCS codes billed by labs, in which labs can bill different sets of HCPCS codes, MBS may be an appropriate fit for our purposes. In MBS, for each HCPCS code in each sampling frame (i.e., physician office, independent, and hospital), we calculated the HCPCS code-specific probability of selection for a lab. For each lab, the MBS probability of selection would be the largest HCPCS code-specific probability of selection from all the HCPCS codes for which the lab has reported testing volume. We can then calculate the expected sample size for all HCPCS codes as the sum of the MBS probabilities of selection.

In 2018, the CLFS included more than 1,300 unique HCPCS codes. Given our resource and time constraints, we selected 10 to evaluate our sampling methods at the HCPCS code level. These 10 codes are a judgmental sample and include codes that rank in the top ten of all codes by testing volume. These 10 codes also include some with large differences between the median price, weighted by testing volume, across independent and hospital labs or across independent and physician office labs. Selecting samples that are representative of each lab type would be most important for these codes. For example, for codes in which independent labs are paid significantly lower prices than hospital labs, if most labs that reported were independent labs, the weighted median prices used for setting CLFS payment rates could be significantly lower than if a representative sample of labs were used to set prices.

By lab type, we compared the payment rates for these 10 codes in each sample with those of the sampling frame, based on payment rates from CMS's data from the first round of reporting private lab payment rates in 2016. We found that MBS produced payment rates that were close to the payment rates from the sampling frame, and much closer compared to stratified sampling. This means that the payment rates calculated using the results from MBS were unbiased, and less biased than the payment rates calculated using stratified sampling results.

To illustrate why our stratified sampling resulted in more biased payment rates compared to MBS, consider a simplified, hypothetical example where there were only two codes: HCPCS code 12345 billed by 10 labs and HCPCS code 67890 billed by 100 labs, which include the 10 labs billing 12345. Our stratified sampling process started with 12345, and in cases where we targeted to sample 10 labs per code, we would sample the 10 labs billing 12345. Since these 10 labs also billed 67890, our sampling would be complete and would include 10 labs. However, the information collected from these 10 labs may not be representative of 67890 since we did not draw a random sample of labs for 67890. In effect, under our stratified sampling method, the HCPCS codes for which only a few labs billed Medicare determined the labs that we sampled for other HCPCS codes, which often resulted in more biased payment rate estimates.

In addition to evaluating the bias of our two sampling methods, we also evaluated the burden associated with each method. We defined burden as the number of labs that would be required to report their private payer rate data to CMS. For our analyses of burden for MBS, we analyzed the cumulative burden of requiring a minimum of 10, 20, or 30 labs to report data for each CLFS HCPCS code, not just the 10 codes we used to examine the accuracy of our methods.

For MBS, we calculated the expected sample size for all HCPCS codes and compared these sample sizes to the number of labs required from a census of all labs. Table ES-1 shows the expected sample sizes by the target number of labs (i.e., 10, 20, or 30 labs per HCPCS code) and lab type. The target sample size is the minimum number of labs sampled for each HCPCS code. The table also includes the number of labs in the independent lab, hospital lab, and physician office lab sampling frames, which would be the number of labs required to report in a census. Finally, the table calculates the expected sample size as a percent of all labs in the frame. For example, for independent labs and a target sample size of 10 labs for each HCPCS code, we found an expected sample size of 867 labs for all HCPCS codes (31% of all 2,772 independent labs). This would remove the reporting burden for 69% of all independent labs when compared to a census. For all three lab types, the expected sample size as a percent of all labs in the frame

ranged from around 30% with a target sample size of 10 labs for each HCPCS code to around half for a target sample size of 30 labs.³

Table ES-1. Expected Sample Sizes for MBS

| Lab Type | Number of Labs in Frame | Target Number of Labs for Each HCPCS Code | Expected Sample Size for MBS | Percent of Labs in Frame |
|------------------|-------------------------|---|------------------------------|--------------------------|
| Independent | 2,772 | 10 | 867 | 31% |
| | | 20 | 1,118 | 40% |
| | | 30 | 1,287 | 46% |
| Hospital* | 3,321 | 10 | 1,139 | 34% |
| | | 20 | 1,572 | 47% |
| | | 30 | 1,828 | 55% |
| Physician Office | 4,627** | 10 | 1,381 | 30% |
| | | 20 | 1,935 | 42% |
| | | 30 | 2,305 | 50% |

Source: RTI International analysis of 2018 Medicare claims data.

Notes: * We limited hospital labs to hospital outreach labs, which are labs that conduct tests for patients not receiving hospital inpatient or outpatient care. ** We restricted physician office labs to those with spending greater than or equal to \$25,000 in 2018. In results shown in Table 3-8, for 10 selected HCPCS codes, we find that restricting physician office labs in this way does not introduce substantial differences between the payment rates calculated from the sampled labs and the payment rates from all physician office labs.

While stratified sampling would also ease the reporting burden of a census, we found that, for some of our 10 selected HCPCS codes, stratified sampling led to large differences between the payment rates from the sampled labs and that of the sampling frame. If a sampling method leads to such differences, reductions in reporting burden may not be worth obtaining biased payment rates, especially if MBS does not result in such differences.

Based on our findings, we believe it is feasible for CMS to collect a representative sample of private payer rates to set accurate lab payment rates. Among the two methods we examined, MBS produced unbiased estimates of payment rates, and were less biased than stratified sampling. MBS also substantially reduced reporting burden on labs. For these reasons, we believe MBS is likely preferable to stratified sampling. However, while this report

³ In our analysis of our 10 selected HCPCS codes, we found that a target sample size of 30 led to payment rates from the resulting samples that were nearly identical to the payment rates from all labs. As a result, we did not examine target sample sizes larger than 30.

demonstrates the feasibility of using MBS to estimate lab payment rates, more work is needed to expand this proof of concept to definitively show that this method can be used to generate representative payment rates for all CLFS HCPCS codes.

SECTION 1.

INTRODUCTION

Clinical laboratory tests provide patients and providers with information that assists with the diagnosis, prevention, and treatment of disease (CMS, 2020). In 2018, clinical lab testing accounted for \$7.6 billion of Medicare spending, with reimbursement rates established by the Clinical Laboratory Fee Schedule (CLFS).⁴ In addition, lab tests influence health care expenditures far beyond their proportion of actual Medicare expenditures because decisions about the provision of other medical services often hinge on lab test results.

The CLFS ties Medicare reimbursement rates to Healthcare Common Procedure Coding System (HCPCS) codes. In 2018, the CLFS established rates for more than 1,330 codes. Medicare pays for clinical lab tests provided in hospital labs, physician office labs, independent labs, dialysis facility labs, nursing facility labs, and other settings (CMS, 2020).

Before 2018, Medicare commonly based payment rates on lab charges from the 1980s, updated to account for inflation, to account for regional variation, and as statutorily required. Some stakeholders criticized this previous method of setting payment rates for overpaying for some longstanding services and underpaying for newer services, relative to private payers. In a 2018 report, the Office of Inspector General for the United States Department of Health and Human Services (OIG) found that Medicare overpaid for lab tests by 18-30% relative to other payers (DHHS, 2013).

In 2018, the Centers for Medicare & Medicaid Services (CMS) began setting payment rates for lab tests using the parameters established in the Protecting Access to Medicare Act of 2014 (PAMA). This legislation updated the manner in which Medicare set payment rates for clinical diagnostic lab tests on the CLFS. PAMA sought to address the gaps between Medicare payment rates and private payer rates by tying Medicare lab payment rates more closely to private payer rates. Specifically, PAMA required CMS to pay labs the median, weighted by testing volume, of private payer rates, as reported by applicable labs.⁵ PAMA and CMS defined applicable labs as labs that billed Medicare Part B under their own billing National Provider Identifiers (NPIs) and that are considered labs under the definition established in the Clinical Laboratory Improvement Amendments of 1988. These labs must also earn more than 50% of

⁴ This \$7.6 billion includes testing billed by hospital labs for patients in the inpatient and outpatient settings that were paid through the CLFS. However, we do not include such testing in the remainder of the report.

⁵ CMS is gradually phasing in reductions to Medicare payment rates. From 2018 through 2020, CMS limited reductions to payment rates annually at 10 percent, as outlined in PAMA (GAO, 2018). CMS is limiting reductions to 0% in 2021 and 15% from 2022 through 2024 (CMS.gov, 2021).

their Medicare revenues through the CLFS or the Physician Fee Schedule (PFS), known as the “majority of Medicare revenues threshold” or “revenue threshold.” Additionally, labs must earn at least \$12,500 from the CLFS during the six-month data collection period to be required to report, the “low expenditure threshold” (CMS, 2018). This low expenditure threshold is meant to reduce the reporting burden for smaller labs (CFR, 2018).

Following the first round of calculations of Medicare payment rates under this new payment system, clinical lab industry stakeholders asserted that CMS was underpaying for lab services because of the preponderant sample of large, independent labs in the payment calculation. Table 1-1 shows the comparison of testing volume by lab type as calculated using 2018 Medicare claims data with the data on private payer rates that CMS collected in 2016. In the data on private payer rates that CMS collected, independent labs represented 90% of the testing volume; we found that these labs represent 49% of Medicare testing volume in 2018. In contrast, hospital labs represented 1% of testing volume in CMS’s data but 28% of Medicare testing volume in our analysis. This comparison indicates that the labs who reported to CMS in 2016 were not representative of the lab market. According to the OIG, because many hospital labs bill for lab services using the provider’s NPI rather than a unique lab-specific NPI, these hospital labs were excluded from data reporting. These hospital labs receive most of their Medicare revenues from other services, not through the CLFS or the PFS. In addition, small physician offices were excluded by the low expenditure threshold.

Hospital labs conduct tests for patients in the inpatient and outpatient settings. Hospital labs also conduct tests for non-hospital patients (those not receiving hospital inpatient or outpatient care) through hospital outreach labs. Hospital outreach labs are paid through the CLFS, while tests for patients in the inpatient and outpatient settings are paid through the Inpatient Prospective Payment System and the Outpatient Prospective Payment System and the CLFS. Table 1-1 also shows that, based on our analysis of the 2018 Medicare claims data, while hospital labs billed for 122 million tests in 2018 (28% of total testing volume), hospital outreach labs billed for 46 million tests (38% of the 122 million total tests billed by hospital labs) and hospital labs performing tests for patients in the inpatient and outpatient settings billed for 76 million tests (62% of total tests billed by hospital labs).

Table 1-1. Comparing Testing Volume by Lab Type from 2018 Medicare Claims with Testing Volume Reported to CMS 2016

| Type of Lab | Testing Volume (in millions) | | | |
|---|--------------------------------------|---|---|--|
| | Medicare Testing Volume - 2018 (RTI) | Percent of Total Medicare Volume - 2018 (RTI) | Private Payer Testing Volume Reported to CMS - 2016 (CMS) | Percent of Total Private Payer Testing Volume Reported to CMS – 2016 (CMS) |
| Independent lab Labs that perform tests independent of an institution or a physician’s office. | 210 | 49 | 224 | 90 |
| Hospital lab Labs that perform tests for patients in the inpatient and outpatient settings and non-patients | 122 | 28 | 2 | 1 |
| <i>Hospital outreach lab</i> <i>Labs that perform test for non-patients</i> | 46 | 11 | N/A | N/A |
| Physician-office lab Labs that are maintained by a physician or group of physicians performing diagnostic tests in connection with the physician practice. | 94 | 22 | 19 | 8 |
| Other Other labs that perform tests paid for by the CLFS, such as those in skilled nursing facilities and dialysis facilities. | 4 | 1 | 3 | 1 |
| Total | 430 | 100 | 248 | 100 |

Source: CMS Report, 2017 and RTI International analysis of 2018 Medicare claims. Lab Definitions: GAO

Note: CMS did not disaggregate testing volume by hospital labs into hospital outreach labs and hospital labs performing tests for patients in the inpatient and outpatient settings.

RTI program reference: LS5

The second round of reporting private lab payment rates is scheduled to take place between January 1, 2022 and March 31, 2022 (CMS.gov, 2021). Ahead of this round, Congress directed the Medicare Payment Advisory Commission (MedPAC) to examine potential alternate methods to CMS’s initial methodology used to set 2018 payment rates. The purpose of this report is to examine options to collect data that would result in a representative and statistically valid sample of the various market segments for each CLFS HCPCS code with the least burden on labs, with a focus on reducing burden for smaller labs for whom reporting would be most

difficult. This study used 2018 Medicare CLFS claims from independent, hospital, physician office, and other labs and data from the 2016 reporting of private payer rates to inform these data collection options.

Section 2 describes the data and methodology used to construct the sampling frames, one for each main lab type (independent, hospital, and physician office). It also describes the three sampling methods assessed in this study: a census, stratified sampling, and Maximal Brewer selection. Section 3 describes the results obtained when testing these sampling methods on Medicare data from 2018, which includes discussion of the tradeoffs between comprehensiveness and burden as well as challenges we encountered. This section also describes hypothetical post-sample selection activities, including mitigating the effect of non-response, reviewing data for quality, and using survey weights. Section 4 concludes with a summary of our results, limitations, and recommendations.

SECTION 2.

DATA AND METHODOLOGY

2.1 Constructing the Sampling Frames

A sampling frame is a list of the information we have available on the population from which we would like to sample. Our goal is to draw samples that are statistically valid and representative of our sampling frames with the least burden to labs. Our sampling frames are lists of labs that billed Medicare through the CLFS in 2018. As discussed below, we defined labs for this analysis using the NPI on a claim, grouping together claims using the same NPI as being billed to a single lab. We used 2018 Medicare claims as this is the most recent year of data available to us. More recent data would be more likely to include tests and labs that will be relevant for CMS's round 2 of reporting. We constructed separate sampling frames for each of the three main lab types (i.e., hospital, physician office, and independent) and drew separate samples for each lab type. Separate sampling frames help us draw samples that are representative of each lab type. If we only constructed one sampling frame for all labs, our sample would be representative of all labs but not necessarily for each lab type.

To construct the sampling frames, we used data from the 2018 100% Medicare Carrier and Outpatient files. The carrier file includes Part B non-institutional claims from physicians, independent labs, and other suppliers, while the outpatient file contains claims from outpatient facilities, including hospital outpatient departments, renal dialysis facilities, and rehabilitation clinics (NCI, 2021). Each claim in these files contains information on the billing providers, payments, and HCPCS codes billed, and can therefore be used to calculate the volume billed for each HCPCS code, the HCPCS codes billed by each provider, and the amount paid for each code, including third party payments. Note that each claim can include multiple lines, each with its own HCPCS code. For simplicity, we refer to claims rather than claim lines.

We included type of bill 14X (hospital outreach) to construct our sampling frame for hospital labs, excluding 12X (hospital inpatient part B) or 13X (hospital outpatient) claims. Hospital outreach lab tests are conducted for patients who are neither admitted to the hospital's inpatient nor outpatient settings. In CMS's round 1 of reporting, few hospitals reported data. However, in CMS's round 2 of reporting, CMS will use 14X claims to determine labs required to report. The Further Consolidated Appropriations Act of 2020 further narrows the mandate of this report from hospital labs broadly to hospital outreach labs (Public Law 116-94). In addition, in future rounds of data reporting, CMS will only require hospital outreach labs to report tests conducted for non-hospital patients (CMS.gov, 2020). Tests conducted by hospital outreach labs

are more comparable to those conducted by independent labs since hospitals have significantly more leverage in setting prices for patients in the hospital's inpatient and outpatient settings. Finally, 14X claims are almost exclusively paid through the CLFS whereas 12X and 13X claims can also be paid through the Inpatient Prospective Payment System and Outpatient Prospective Payment System (U.S. GAO, 2018).

We used NPIs to identify individual labs. While some labs, such as Quest and LabCorp, may use many NPIs to bill Medicare, CMS defines labs using NPIs in their methodology for setting CLFS rates. In addition, it is difficult to group NPIs into larger organizations. In the carrier file, we used the NPI used to bill the service and in the outpatient file, we used the organization's NPI. We used service units to calculate the testing volume associated with a given HCPCS code or a lab. For payments, we calculated a total payment variable by summing the Medicare, beneficiary, and third-party payments, if any. We calculated the testing volume and amount paid to each lab for each HCPCS code by aggregating the testing volume and total payment for each HCPCS code at the NPI-level.

Table 2-1 lists all the exclusion criteria we applied to construct our sampling frames. For example, we included only HCPCS codes listed in the 2018 CLFS, removing any non-lab codes from our analysis. Note that HCPCS codes with no claims associated were excluded from this analysis because there would be no claims available to sample (see Appendix A for the list of HCPCS codes with no claims in 2018). We also excluded claims for 24 HCPCS codes on specimen collection, travel allowances, and unlisted lab codes, as these are either not considered lab tests or are not priced based on private payer rates (see Appendix B for a list of these 24 HCPCS codes). In addition, we excluded claims in the carrier file with allowed charges or amount paid equal to zero, since we focus on claims that Medicare will and did pay. In the outpatient file, we excluded claims with an amount paid equal to zero.

We categorized labs into four different types: hospital, physician office, independent, and other labs. For the carrier file, we used the claim's place of service to categorize labs into independent (place of service of 81), physician office (place of service of 11), and other lab (all other places of service). If a lab billed across multiple places of service (roughly 8% of labs in the carrier file), we assigned the lab to the lab type in which the lab billed the plurality of its testing volume. For labs where there were equal testing volume billed between two or more places of service, we randomly assigned the lab to a type. For the outpatient file, we categorized the lab as a hospital lab if the plurality of its claims had type of bill 14X (hospital outreach). Remaining labs were categorized as other. For labs that were in both the carrier and outpatient files, we categorized these labs based on which lab type the plurality of their claims was billed.

Table 2-1. Exclusion Criteria for Constructing Our Sampling Frames

| Exclusion | Rationale |
|--|--|
| Claims with non-CLFS HCPCS codes | Payment rates for codes not paid through the CLFS are not set using private payer rate data. |
| Claims with allowed charges or amount paid of \$0 | Eliminates non-paid claims. |
| Outpatient claims for CLFS HCPCS codes not paid through the CLFS | Payment rates for claims not paid through the CLFS are not set using private payer rate data. For example, we excluded claims with type of bill 14X without a revenue center status indicator code of “A”; such claims are paid through other payment systems, such as the Outpatient Prospective Payment System, and not the CLFS. Please see Appendix C for details. |
| Claims with Type of Bill 12X and 13X | We excluded claims for hospital inpatient and outpatient services. Please see the discussion above for our rationale. |
| HCPCS codes for specimen collection, travel allowances, and unlisted lab codes | These codes are excluded because they are not lab tests or are not priced based on private payer rates. Please see Appendix B for a list of these codes. |
| Claims billed by placeholder NPIs 999999992 from the carrier file and 999999996 from the outpatient file | We cannot identify the labs corresponding to these placeholder NPIs and therefore would not be able to sample them. |
| Exclude the professional component of claims for CLFS codes | Claims for some CLFS codes include both a professional component and a lab component. Claims for the professional component is billed through the Medicare physician fee schedule and not the CLFS. As a result, we exclude the claims for the professional component and include the claims for the lab component. |

Source: RTI International analysis of 2018 Medicare claims.

2.2 Sampling

Given the requirement to estimate private payer rates for each HCPCS code, in addition to a census, which involves collecting data from all labs in our sampling frames, we evaluated two sampling methods: stratified sampling and MBS. Some of the possible advantages of sampling are the reduced cost of data collection and reporting burden and greater speed of data collection. Stratified sampling is a commonly used sampling method that divides the sampling frames into mutually exclusive and exhaustive subpopulations, known as sampling strata. One then samples independently from the sampling strata. Our second sampling method, MBS, has been used to sample farms producing a variety of crops. This is analogous to sampling labs conducting a variety of tests, which is why MBS may be suitable here.

In conducting our sampling, we relied on two sources of data: Medicare claims and private payer rate data reported to CMS in 2016. We used Medicare claims data to construct our

sampling frames and the testing volume and payment for each lab-HCPCS code combination. This allowed us to draw our samples. Once we drew our samples, we used the private payer rate data to examine the accuracy and precision of our sampling results.

Table 2-2 lists some terms we use to describe our sampling methods and results, their definitions, and their application when sampling labs.

Table 2-2. Terms Used to Describe Our Sampling Methods

| Term | Definition | Application to Sampling Labs |
|-------------------|--|--|
| Target population | The complete list of entities that we want to study. | List of labs that we want to study |
| Sampling frame | The list of entities from which the sample will be selected. The sampling frame should be as close as possible to the target population. | List of labs from which we select the sample; we constructed three sampling frames, one for each lab type (physician office, hospital outreach, and independent) |
| Sampling unit | An entity that can be selected for the sample. | A lab |
| Sampling strata | Exhaustive and mutually exclusive groups of sampling units within which sampling is conducted independently. | A HCPCS code |

Source: RTI International

2.2.1 Stratified Sampling

Typically, in stratified sampling, sampling units are unique to each sample strata. For example, if we are sampling people by age and sex categories, each person (the sampling unit) is only in one age-sex category (sampling strata). However, in sampling labs, most labs bill for multiple HCPCS codes. This presents challenges to our sampling process. First, labs are only allowed to be in one HCPCS code stratum for sample selection in stratified sampling (although once sampling is completed, a lab can report information on more than the one code for which they are selected). Because of this, one challenge is determining in which HCPCS code stratum to place a lab for sampling.

Second, prior to sampling, we cannot calculate an overall sample size for all HCPCS codes because of the interrelationship of HCPCS codes within a lab. Consider two extreme hypothetical examples. In the first example, all labs bill for only one HCPCS code. If we target to sample 10 labs for each HCPCS code, the resulting sample size would be roughly 13,000 labs since there are around 1,300 CLFS HCPCS codes. In the other extreme, if all labs bill for all 1,300 CLFS HCPCS codes, the resulting sample size would be 10 labs since these 10 labs would cover all codes. However, our challenge is that neither example is accurate and our resulting

sample size would be somewhere in between these two extremes but cannot be determined prior to sampling. In addition, the labs would not have the same probability of selection across HCPCS codes. A lab's probability of selection depends on its testing volume relative to the total testing volume in a HCPCS code.

Finally, the order of sampling is critical. As a simplified, hypothetical example, consider if there were only two codes: a HCPCS code 12345 billed by 10 labs and another code 67890 billed by 100 labs, which include the 10 labs billing 12345. If we start our sampling process with 12345 and we are targeting to sample 10 labs per code, we would sample the 10 labs billing 12345. We refer to the 10 labs billing 12345 as "certainty" labs since these labs would be included in our sample with certainty. In addition, since these 10 labs also bill 67890, our sampling would be complete for both HCPCS codes and would include only 10 labs. However, the information collected from these 10 labs may not be representative of 67890. On the other hand, if we start our sampling process with 67890, we may select labs that do not also bill 12345. As a result, our sampling would potentially include more than 10 labs. However, the information collected from our sample would be likely be more representative of both 67890 and 12345.

For our version of stratified sampling, we used a two-stage sampling procedure to ensure that we met the target sample size in each HCPCS code sampling stratum. The target sample size is minimum number of labs included in the sample. In the first stage, we selected all labs that were in HCPCS code sampling strata that had a lab count less than or equal to the targeted sample size (i.e., certainty labs). After the first stage of selection, we removed the HCPCS codes and labs selected in the first stage and assessed how many more labs were required to meet the target sample size for all remaining HCPCS code sampling strata. After the assessment, if an HCPCS code sampling stratum required additional labs for the sample size to attain the target sample size, we conducted the second stage of sampling. The second stage of sampling implemented systematic probability proportional-to-size sampling⁶ in the remaining HCPCS code sampling strata to meet the target sample size requirement.

⁶ Systematic probability proportional-to-size sampling consists of five steps: 1) Ensure that each lab has testing volume greater than zero. 2) Sort the sampling frame in some type of order (it could be a random ordering). 3) Calculate the adjusted testing volume for a lab as the target sample size times testing volume. 4) Calculate the cumulative range for the labs: for the first lab on the list, the lower bound is 1 and the upper bound is the adjusted testing volume. For the remaining labs, the lower bound of the current lab is the upper bound of the previous lab + 1. The upper bound of the current lab is the upper bound of the previous lab plus the current lab's adjusted testing volume. 5) Generate a random number, r , between 1 and the sum of the original testing volumes. Select the labs that have the values r , r + the sum of the original testing volumes, r + 2 times the sum of the original testing volumes, ..., (sample size - 1) times the sum of the original testing volume.

The target sample size can be chosen through a normative process by weighing the burden versus increased accuracy of sampling additional labs. In our analysis, the target number of labs per sampling stratum is the same, but the target number of sampling units could vary for each sampling stratum. For example, if we found that a target sample size of ten labs was enough to provide an accurate picture of the price of a HCPCS code for independent labs but other lab types required a target sample size of 40, we could vary the target sample size to maximize accuracy while minimizing reporting burden across lab types.

Some HCPCS codes were billed by only a few labs. We prioritized the HCPCS codes for which the number of labs was less than the target sample size per HCPCS code, effectively allowing us to draw a census of the labs that offer these codes. As discussed above, we refer to these labs as certainty labs and this part of the sample as the certainty part of the sample. For example, if we wanted to sample at least 10 labs for each HCPCS code, we started our sampling process by collecting information on HCPCS codes billed at fewer than 10 labs. This prioritization would help minimize the number of labs sampled, although potentially at the expense of producing biased estimates for other HCPCS codes.

In the second stage, after removing the labs selected in the certainty part of the sample, we proceeded to the probability part of the sample. The sampling frame for this stage included the HCPCS codes for which the number of labs exceeded the target sample size per HCPCS code and the target sample size had not been met by the certainty labs. For this stage, we used stratified systematic probability proportional-to-size sampling to ensure that there is a target, or target plus one, number of selected sampling units in a sampling stratum (i.e., a target number of selected labs for each HCPCS code). Because we reduced the number of potential labs that could be sampled in this step by removing certainty labs from our sampling frame in the previous step, there is the possibility of additional certainty labs being identified in the probability part of the sample. If there were any such labs, they were added to the certainty labs. For the remaining labs, the target sample size and the probabilities of selection were recalculated and the process repeated.

We describe the detailed steps we implemented to select our samples.

1. Specify the minimum number of labs, which we define as the target sample size, that we want in the sample for each HCPCS code (e.g., 10 labs). For simplicity, we set the target sample size to be the same for each HCPCS code, but one could vary the target sample size based on the number of labs in the sampling stratum or some other criterion.
2. Calculate the number of labs billing each HCPCS code based on the frame information.

3. If the number of labs for a HCPCS code was less than or equal to the target sample size, designate the labs as certainty labs, remove them from the sampling frame, and put them into the certainty frame. Call the labs remaining in the sampling frame the “current” frame.
4. For the labs in the certainty frame, calculate the number of labs in each HCPCS code.
5. For each HCPCS code, reduce the target sample size by the number of certainty labs to create the updated target sample size.
6. Once there are no more certainty labs in the current frame, for each HCPCS code, calculate the probability of selection for each lab. We describe how we calculated the probability of selection in section 2.2.3.
7. For each HCPCS code, if the probability of selection of a lab is greater than or equal to one, designate the lab as a certainty lab. The probability of selection may be greater than one if a lab billed a disproportionate share of the testing volume for the code. For example, if there are five labs for a HCPCS code and one of the labs accounted for half of the testing volume, that lab would have a probability of selection greater than one if we need to select four of the five labs for that HCPCS code. Please see section 2.2.3 for details on how we calculated the probability of selection.
8. Once we have probabilities of selection for all labs for each HCPCS and have done this calculation for all HCPCS codes, remove all the certainty labs from the current frame, and add them to the certainty frame.
9. For each HCPCS code, reduce the updated target sample size by the number of certainty labs added to the certainty frame.
10. Repeat steps 8-9 until there are no more certainty labs. This may be an iterative process.
11. Finally, for each HCPCS code, select the most recent updated target sample size using systematic probability proportional-to-size.

We assumed that certainty labs would provide data on all HCPCS codes for which they have data, but labs selected in the probability part of the sample would only provide information for the HCPCS code for which they are sampled. If the labs selected in the probability part of the sample provided information for all HCPCS codes, it would require a more complicated sampling process that would involve a dynamic, iterative process that depends on the order of the HCPCS codes and which labs get selected for each HCPCS code. For a hypothetical example, if lab A tests for 100 HCPCS codes and lab A is selected for HCPCS code 12345, lab A’s probability of selection for the remaining 99 HCPCS codes would be 1, which would affect the selection probability for the other labs for these remaining 99 HCPCS codes (e.g., if one of these codes had 50 labs with equal testing volume and the target sample size is 10, prior to lab A’s

selection for code 12345, each lab would have a 1 in 5 chance of being selected; after lab A's selection for code 12345, each remaining lab would have a 9 in 49 chance of being selected). As a result, the selection of labs for one code would affect the selection of labs for other codes and potentially vice versa, leading to an iterative process that also depends on the order of the HCPCS codes. In future work, one could explore alternative strategies so that all sampled labs would provide information for all HCPCS codes for which they have data, this would reduce the number of sampled labs.

Even though we planned for the probability part of the sample, for our analysis, we rarely implemented the probability part of the sample for the 10 HCPCS codes on which we focused. This is because the certainty labs alone enabled us to reach our target sample sizes for almost all of the selected HCPCS codes.

2.2.2 *Maximal Brewer Selection (MBS)*

A more innovative sampling approach that would not require explicit stratification by HCPCS code is a version of MBS as described in Kott and Bailey (2000). MBS has been used to collect crop data from farms, because a single farm can grow a variety of crops, and different farms grow different sets of crops. It does this by determining an optimal probability of selecting a farm for each crop individually and then setting the probability of choosing a lab at its highest individual-crop selection probability. Since labs bill different sets of HCPCS codes, a version of MBS may also be an appropriate sampling design for lab testing.

We implemented a maximal probability proportional-to-size selection, which is a version of MBS. However, for simplicity, we refer our method as MBS for the remainder of the report. To implement this version of MBS, we implement the following. For each HCPCS code in each sampling frame (i.e., physician office, independent, and hospital), we calculated the HCPCS code-specific probability of selection for a lab. The probability of selection for a specific HCPCS code is the target sample size for the HCPCS code times the lab-specific HCPCS code testing volume divided by the total HCPCS code testing volume for all labs for the HCPCS code in the sampling frame. We describe how we calculated the probability of selection in section 2.2.3. For each lab, the MBS probability of selection would be the largest HCPCS code-specific probability of selection from all the HCPCS codes for which the lab has reported testing volume.

We used Poisson sampling to select the MBS sample (i.e., each lab was chosen independently using its MBS probability of selection). This results in a random sample size. Every eligible lab has a probability of selection greater than zero. Since we use probability proportional-to-size sampling, a lab's probability of selection is proportional to its testing

volume. Therefore, labs have different probabilities of selection based on their testing volume. For Poisson sampling, a random number on the interval from zero to one is generated. If the random number is less than or equal to the probability of selection, the lab is selected into the sample. The reason the sample size is random is that selection is done independently so that there is no fixed sample size. That is, a different set of random numbers can give a different sample size. However, in future work, one could consider using systematic probability proportional-to-size, where the expected sample size will be the same, but the actual sample size will be restricted to either the expected sample size or one of the two integers closest to the expected sample size.

We describe the detailed steps we implemented to select our samples:

1. Specify the target number of labs that we want in each HCPCS code. Call this the target sample size. The target sample size is the same for each HCPCS code, but one could vary the target sample size based on the number of labs that bill each HCPCS code or some other criterion.
2. For each HCPCS code, calculate the probability of selection. We describe how we calculated the probability of selection in section 2.2.3.
3. For each HCPCS code, if the probability of selection of a lab is greater than or equal to one, set it to one.
4. Now that we have probabilities of selections for all HCPCS codes, the maximal probability proportional-to-size probability of selection for the i^{th} lab is the largest probability of selection across all the HCPCS codes for which the i^{th} lab has testing volume.

2.2.3 *Probability of Selection*

For stratified sampling, once we remove all the certainty labs from the sampling frame, we calculate the probability of selection for the remaining labs. In particular, let $U_t = \{1, \dots, N_t\}$, for target t (i.e., a HCPCS code), be the set of labs that billed at least one test for target t . The probability of selection for the i^{th} lab in U_t , p_{ti} , is

$$p_{ti} = n_t \frac{m_{ti}}{\sum_{j \in U_t} m_{tj}}$$

where n_t is the sample size for target t , m_{ti} is the measure of size (volume of tests) for the i^{th} lab in U_t . For each target t , if any of the p_{ti} are greater than or equal to one, set p_{ti} equal to one, designate it as certainty unit, and remove it from the sampling frame. A new set of p_{ti} is calculated using the original sample size minus the number of certainty units. These two steps

are iteratively implemented until there are no more certainty units. The sample selection proceeds on the reduced sampling frame for target t . It is reasonable to assume before they are collected that the prices labs charges for a code are roughly independent and identically distributed. Under probability-proportional-to-size sampling, where the probability of selection is weighted by the size (testing volume), the resulting unbiased estimate of the average price has the smallest expected variance (Kott, 1984).

For MBS sampling, the probabilities of selection in each HCPCS code are calculated like the probabilities of selection in the stratified sampling example above. The additional step to get the MBS probability of selection for a lab is to look across all HCPCS codes for which the lab has a HCPCS specific probability of selection and select the largest HCPCS-specific probability of selection to be the MBS probability of selection.

$$\pi_i = \max_t \{p_{ti}\}$$

2.2.4 Use of Private Payer Rates Data to Estimate Distributions of Payment Rates by HCPCS Code and Lab Type

In the previous section, we described how we used Medicare claims data to set up our sampling frame and sampling strata. In this section, we describe how we used private payer data reported to CMS in 2016 to estimate distributions of payment rates by HCPCS code and lab type, which allows us to validate our sampling method against the census used by CMS in 2016. To examine the accuracy and precision of our sampling results, we simulated payment rates received by labs for each HCPCS code in our sampling frames using the private payer rate data reported to CMS in 2016. We simulated payment rates for labs since data from the previous data collection process was limited for our purposes. For example, some labs in our sampling frame, which was constructed using 2018 Medicare claims data, are not included in the private payer rate data reported to CMS in 2016. For this simulation, we calculated the means and standard deviations of the log of the payment rates received by labs for each HCPCS code in the private payer rate data that CMS used to set the 2018 CLFS payment rates. We generated random numbers from a lognormal distribution with these means and standard deviations to simulate payment rates for each lab and HCPCS code in our sampling frames.⁷ This allowed us to assess whether our sampling produced any bias in payment rates by comparing the mean payment rate in the sample to the mean payment rate from the private payer rate data. In addition, because

⁷ Using the private payer rate data, we examined the distribution in payment rates for our 10 selected HCPCS codes by lab type and found that these payment rates generally followed a lognormal distribution. However, there were exceptions. For example, since the private payer rate data only includes payment rates from a handful of hospital labs, some of our selected HCPCS codes only included payment rates for a few hospital labs. Nonetheless, for simplicity, we used a lognormal distribution for all 10 HCPCS codes and all lab types.

CMS sets payment rates based on the median payment rate weighted by testing volume, we also calculate another measure of bias that compares the weighted median payment rate in the sample to that of the private payer rate data. We also calculated the variation in payment rates from our sample. We conducted this analysis separately by lab type since we constructed separate sampling frames by lab type. While the private payer rate data was based on payment rates by labs in the first half of 2016, it is the best available source of information on payment rates paid by private payers.

This private payer rate data included the NPI of each reporting lab, the HCPCS code for which the lab reported, the payment rate paid by private payers, and the testing volume associated with the payment rate. If a lab received more than one payment rate from private payers, the private payer rate data included more than one observation, one for each distinct payment rate. Because the private payer rate data did not include the lab type, we created a list of labs and their lab type from our analysis of the 2018 Medicare claims. We merged this list onto the private payer rate data to calculate the mean and standard deviation of the payment rate for each HCPCS by lab type. However, because the private payer rate data reflected what labs reported for the first half of 2016 and we used Medicare claims for 2018, we were unable to identify the lab type for all labs in the private payer data. For example, if a lab that reported payment rates for 2016 closed in 2017, we would not know the lab type for this lab from the 2018 claims data.

In our analysis of our sampling results, we selected HCPCS codes as illustrative examples. In 2018, the CLFS included more than 1,300 unique HCPCS codes. As a result, we selected 10 to evaluate how our sampling methods worked at the HCPCS code level. We chose 10 as a reasonable number to examine for this proof of concept and due to time and resource constraints. To select these HCPCS codes, we used a variety of criteria. Some of these criteria were based on our analysis of private payer rate data. First, we selected codes that ranked highest in terms of testing volume since these codes would be important for the CLFS as they would affect the most tests. Second, we selected codes with large differences between the median price, weighted by testing volume, across independent and hospital labs or across independent and physician office labs. Selecting samples that are representative of each lab type would be most important for these codes. For example, for codes in which independent labs charged significantly lower prices than hospital labs, if most labs that reported were independent labs, the weighted median prices used for setting CLFS payment rates would be significantly lower than prices charged by hospital labs. In addition to these criteria, we also selected codes in which we were able to map over 90% of the testing volume in the private payer rate data to a lab type. For

example, if a code was reported by many labs in the private payer rate data that were not in our list of labs and lab types from the 2018 Medicare claims, the weighted median price among the labs that we were able to categorize by lab type would only be based on the small portion of labs we were able to categorize. Finally, we also ensured that the selected codes had sufficient testing volume for each lab type (i.e., at least 100 tests billed each by independent, hospital, and physician office labs). The judgmental sample that resulted is only for illustrative purposes and is not intended to be representative of all CLFS codes. More work would be needed to expand this proof of concept to definitively evaluate our methods for all HCPCS codes.

2.2.5 Estimation

For both sampling methods, we implemented almost the same methodology to estimate the payment rate and variance for each HCPCS code from the sample. The only difference is the probability of selection that is used. For stratified sampling, the ratio estimate of the price, the weighted total revenue divided by the weighted volume of tests, for target t , \hat{r}_t , is

$$\hat{r}_t = \frac{\sum_{i \in S_t} w_{ti} y_{ti}}{\sum_{i \in S_t} w_{ti} x_{ti}}$$

where S_t is the sample for target t , y_{ti} is the total revenue for the i^{th} lab in target t , x_{ti} is the test volume for the i^{th} lab in target t , and w_{ti} is the design weight (for the specific HCPCS code) for the i^{th} lab in target t . We calculated revenue as the product of each lab's payment rate (simulated from the private payer rate data) and each lab's testing volume (calculated from our analysis of the 2018 Medicare claims data) for the specific HCPCS code.

$$w_{ti} = \begin{cases} \frac{1}{p_{ti}}, & \text{if selected for the sample} \\ 0, & \text{otherwise} \end{cases}$$

Using where Z_t as the set of labs in the non-certainty part of the sample for variance estimation, the estimated price for target t , \hat{r}'_t , is

$$\hat{r}'_t = \frac{\sum_{i \in Z_t} w_{ti} y_{ti}}{\sum_{i \in Z_t} w_{ti} x_{ti}}$$

For the each HCPCS code in stratified sampling, using the estimated price for target t , the estimated variance for the estimated price of target t , \hat{v}_t , is

$$\hat{v}_t = \left(\frac{n_t}{n_t - 1} \right) \frac{\sum_{i \in Z_t} (1 - p_{ti}) w_{ti}^2 (y_{ti} - \hat{r}'_t x_{ti})^2}{\left(\sum_{i \in Z_t} w_{ti} x_{ti} \right)^2}$$

where n_t , is the number of labs in the non-certainty part of the sample.

For MBS, the ratio estimate of the price, the weighted total revenue divided by the weighted volume of tests, for target t , \hat{r}_t , is

$$\hat{r}_t = \frac{\sum_{i \in S_t} \pi_i d_i y_{ti}}{\sum_{i \in S_t} d_i x_{ti}}$$

where π_i is the MBS probability of selection and the design weight, d_i , is

$$d_i = \begin{cases} \frac{1}{\pi_i}, & \text{if selected for the sample} \\ 0, & \text{otherwise} \end{cases}$$

and y_{ti} and x_{ti} are the same as in stratified sampling. Again, using where Z_t as the set of labs in the non-certainty part of the sample for variance estimation, the estimated price for target t , \hat{r}'_t , is

$$\hat{r}'_t = \frac{\sum_{i \in Z_t} d_i y_{ti}}{\sum_{i \in Z_t} d_i x_{ti}}$$

The estimated variance is

$$\hat{v}_t = \left(\frac{n_t}{n_t - 1} \right) \frac{\sum_{i \in Z_t} (1 - \pi_i) d_i^2 (y_{ti} - \hat{r}'_t x_{ti})^2}{\left(\sum_{i \in Z_t} d_i x_{ti} \right)^2}$$

SECTION 3. RESULTS

3.1 Sampling Frames

3.1.1 Overall Summary Statistics

Based on our analysis of 2018 Medicare claims, Table 3-1 shows summary statistics by lab type. We calculated the number of labs, the testing volume, the percent of total testing volume, the payment, percent of total payment, and the number of HCPCS codes with at least 1 test billed for Medicare in 2018. For Medicare in 2018, almost 62,000 labs conducted over 350 million tests and were paid more than \$6.5 billion. While the number of independent labs is the lowest of the lab types, independent labs represent almost 60% of total testing volume and 70% of total payment. Independent labs are larger than other labs. In addition, independent labs representing more of the total payment than the total testing volume suggests that independent labs conduct tests with higher payment rates. We found over 50,000 NPIs that were physician office labs, representing 27% of testing volume and 20% of payment. However, as shown below in Table 3-4, many of these labs billed less than 100 tests to Medicare in 2018. Hospital labs were third largest in number, representing 13% of testing volume and 10% of payment. Of the over 1,300 CLFS codes in 2018, 1,243 were billed at least once. Of these, independent labs billed 1,197 codes at least once, hospital labs billed 1,105, and physician office labs billed 1,038. Other labs include a variety of different types of labs, including skilled nursing facility and end-stage renal disease facility labs. However, these other labs only represented 1% of testing volume and payment in 2018. As a result, we do not include results for other labs in our subsequent discussion.

Table 3-1. Summary Statistics by Lab Type, 2018

| Lab | | Testing | | Number of HCPCS Codes With At Least 1 Test Billed For Medicare In 2018 | | |
|------------------|---------------|-------------------------|-------------------------------|--|--------------------------------|--------------|
| Type | Number | Volume (in millions) | Percent of Total Volume | Payment (in millions), \$ | Percent of Total Payment | |
| Independent | 2,772 | 210 | 59 | 4,560 | 70 | 1,197 |
| Hospital | 3,321 | 46 | 13 | 656 | 10 | 1,105 |
| Physician office | 51,405 | 94 | 27 | 1,299 | 20 | 1,038 |
| Other | 4,305 | 4 | 1 | 37 | 1 | 708 |
| Total | 61,803 | 353 | 100 | 6,553 | 100 | 1,243 |

Source: RTI International analysis of 2018 Medicare claims.

RTI program reference: LS5

3.1.2 *Summary Statistics for Selected Codes*

Of the over 1,300 CLFS codes, we selected 10 HCPCS codes as illustrative examples. We discuss the criteria we used for selecting these codes in the methods section. Since this is a judgmental sample of codes, the results for these codes are not generalizable to all CLFS codes. In Table 3-2, for these 10 codes, we show how the code ranks among the over 1,300 codes in terms of testing volume and payment, the number of labs, testing volume, total payments, percent of total payments, and the weighted median price from the private payer rate data. Except for the weighted median price, all other information is from our analysis of 2018 Medicare claims.

For context, in 2018, the median number of labs, testing volume, and payment for all codes were 107 labs, 3,332 tests, and \$101,489. The maximums were 26,513 labs, around 34 million tests (for 80053, one of the codes we selected), and around \$436 million (also for 80053). There were also around 90 codes with 0 tests in 2018. Appendix D provides additional context for our 10 selected HCPCS codes by graphically depicting how our 10 selected codes compare with the other CLFS HCPCS codes with nonzero testing volume in terms of testing volume and proportion of testing volume billed by independent labs. Three of the codes we selected are in the top 5 in terms of testing volume and the top 8 in terms of payment. Other codes were not among the top codes in terms of testing volume or payment but had large differences between the weighted median price charged by independent and hospital labs and between independent and physician office labs. For example, for 87902, the weighted median price charged by physician office labs was over 70% higher than the price charged by independent labs. 86% of the payment was to independent labs in 2018.

Table 3-2. Testing Volume and Payment for Select HCPCS Codes, Overall and by Lab Type

| HCPCS | | Rank | | Lab | | Testing Volume | Payment, \$ | Percent of Total Payment, % | Weighted Median Price from Private Payer Rate Data, \$ |
|-------|-------------------------------|--------|---------|------------------|--------|----------------|-------------|-----------------------------|--|
| Code | Code Description | Volume | Payment | Type | Number | | | | |
| 80053 | Comprehensive metabolic panel | 1 | 1 | All | 10,373 | 33,960,897 | 436,384,500 | 100 | 9.08 |
| | | | | Independent | 1,636 | 20,830,933 | 265,685,282 | 61 | 8.86 |
| | | | | Hospital | 3,049 | 5,053,458 | 67,242,040 | 15 | 11.73 |
| | | | | Physician office | 4,941 | 7,847,449 | 100,528,289 | 23 | 14.08 |
| 80061 | Lipid panel | 3 | 2 | All | 45,398 | 28,642,221 | 361,799,453 | 100 | 11.23 |
| | | | | Independent | 1,707 | 14,096,615 | 227,917,760 | 63 | 10.67 |
| | | | | Hospital | 4,910 | 9,461,071 | 51,176,738 | 14 | 17.13 |
| | | | | Physician office | 37,649 | 4,997,414 | 81,288,983 | 22 | 18.23 |
| 83036 | Glycosylated hemoglobin test | 5 | 8 | All | 17,619 | 16,773,277 | 197,285,561 | 100 | 8.50 |
| | | | | Independent | 1,491 | 9,488,147 | 111,351,615 | 56 | 8.49 |
| | | | | Hospital | 2,824 | 1,879,010 | 22,261,064 | 11 | 13.01 |
| | | | | Physician office | 12,460 | 5,283,829 | 62,237,807 | 32 | 13.24 |
| 86003 | Allergen specific ige | 25 | 54 | All | 1,307 | 3,100,747 | 19,517,319 | 100 | 4.65 |
| | | | | Independent | 327 | 2,414,151 | 15,174,071 | 78 | 4.62 |
| | | | | Hospital | 749 | 200,193 | 1,261,381 | 6 | 7.12 |
| | | | | Physician office | 214 | 485,550 | 3,076,658 | 16 | 7.39 |
| 82378 | Carcinoembryonic antigen | 80 | 73 | All | 2,658 | 629,060 | 14,445,357 | 100 | 16.90 |
| | | | | Independent | 842 | 312,715 | 7,169,749 | 50 | 16.80 |
| | | | | Hospital | 1,405 | 68,551 | 1,584,639 | 11 | 25.81 |
| | | | | Physician office | 380 | 247,232 | 5,677,468 | 39 | 27.70 |

(continued)

Table 3-2. Testing Volume and Payment for Select HCPCS Codes, Overall and by Lab Type (continued)

| HCPCS | | Rank | | Lab | | Testing Volume | Payment, \$ | Percent of Total Payment, % | Weighted Median Price from Private Payer Rate Data, \$ |
|-------|-------------------------------|--------|---------|------------------|--------|-------------------|-------------|-----------------------------------|--|
| Code | Code Description | Volume | Payment | Type | Number | | | | |
| 84445 | Assay of tsi globulin | 327 | 240 | All | 879 | 40,840 | 2,485,030 | 100 | 43.70 |
| | | | | Independent | 232 | 34,484 | 2,106,343 | 85 | 42.62 |
| | | | | Hospital | 579 | 5,578 | 334,555 | 13 | 68.17 |
| | | | | Physician office | 59 | 673 | 37,970 | 2 | 71.36 |
| 86148 | Anti-phospholipid antibody | 304 | 357 | All | 304 | 47,432 | 910,474 | 100 | 14.31 |
| | | | | Independent | 133 | 40,915 | 784,117 | 86 | 14.31 |
| | | | | Hospital | 146 | 1,674 | 32,280 | 4 | 22.08 |
| | | | | Physician office | 20 | 4,780 | 92,886 | 10 | 22.58 |
| 87902 | Genotype dna/rna hep c | 376 | 117 | All | 946 | 28,620 | 8,728,292 | 100 | 224.32 |
| | | | | Independent | 241 | 24,399 | 7,496,851 | 86 | 215.81 |
| | | | | Hospital | 651 | 3,873 | 1,129,694 | 13 | 331.48 |
| | | | | Physician office | 42 | 221 | 63,072 | 1 | 373.07 |
| 87150 | Dna/rna amplified probe | 425 | 368 | All | 357 | 20,594 | 831,555 | 100 | 30.10 |
| | | | | Independent | 88 | 15,922 | 638,229 | 77 | 30.03 |
| | | | | Hospital | 240 | 4,162 | 171,578 | 21 | 75.48 |
| | | | | Physician office | 22 | 301 | 12,911 | 2 | 39.21 |
| 88262 | Chromosome analysis 15-20 | 586 | 349 | All | 182 | 6,567 | 991,966 | 100 | 125.49 |
| | | | | Independent | 83 | 4,535 | 684,042 | 69 | 121.55 |
| | | | | Hospital | 86 | 538 | 83,791 | 8 | 166.02 |
| | | | | Physician office | 13 | 1,494 | 224,134 | 23 | 166.43 |

Source: RTI International analysis of 2018 Medicare claims and CMS private payer rate data.

Note: Except for the weighted median prices, all other information based on analysis of 2018 Medicare claims.

3.1.3 Testing Volume by Lab

Figure 3-1 shows the distribution of Medicare Fee-For-Service testing volume by lab for each lab type. Note that the x-axes for the independent and hospital labs are in the thousands of tests whereas the x-axis for the physician office labs are the number of tests. For all lab types, the distribution is skewed heavily to the right. For independent labs, 1,855 labs (67% of all independent labs) billed Medicare for 5,000 or fewer tests whereas 337 billed more than 50,000 tests. For hospital labs, 2,554 labs (767%) billed 10,000 or fewer tests whereas 93 billed more than 100,000 tests. Physician office labs are much smaller, 39,522 labs (77%) billed fewer than 550 tests.

Table 3-3 also shows the distribution of testing volume by lab for each lab type. The top labs have testing volumes orders of magnitude higher than the median lab. In the most extreme case, the top independent lab's testing volume is more than 11,000 times the testing volume of the median lab. In addition, the top 5 independent labs comprise around 20% of the testing volume. Even this is an under-estimate since this distribution is by NPI and the top independent labs use multiple NPIs. As a result of this skew, the mean lab has higher testing volume than the lab at the 75th percentile.

When comparing across lab type, while the top independent labs have higher testing volume than the top hospital and physician office labs, the median hospital lab has higher testing volume than the median independent lab. The median physician office lab is significantly smaller with only 108 tests.

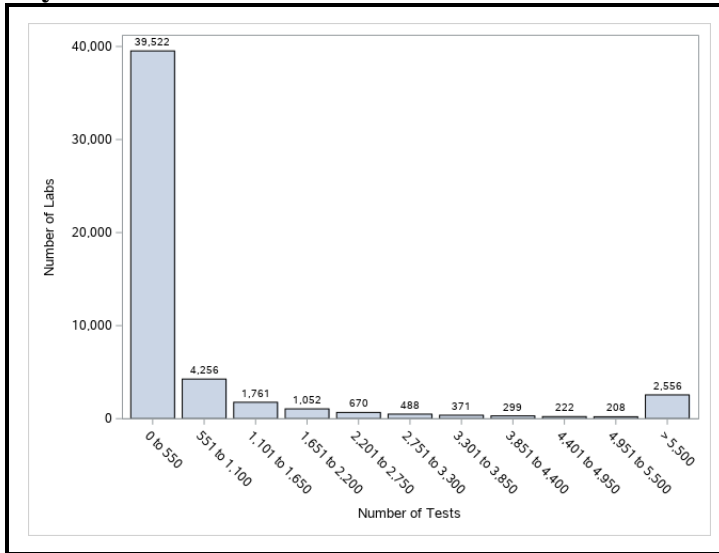
Because of the distribution in testing volume by lab is heavily skewed to the right with a large portion of labs having relatively low testing volume, setting a threshold for labs to be included in the frames used for sampling would eliminate the reporting burden for most small labs without significantly affecting the payment rates estimated from the sample. These labs could still be included when calculating the weights, using testing volume, used to set the CMS payment rate, which would improve the representativeness of the CMS payment rate while reducing burden on small labs. In particular, when one combines the private payer rates from independent, hospital, and physician office labs, one could include the testing volume of the small labs excluded from the sample to weight the private payer rates. The drawback for setting a threshold is that it assumes that smaller and larger labs of the same type have similar private payer rates. However, smaller labs may have significantly different private payer rates compared to larger labs. For example, smaller labs may have less leverage when negotiating rates with payers compared to larger labs, which would lead to lower rates for smaller labs. On the other

hand, smaller labs may not be able to take advantage of economies of scale compared to larger labs, which would lead to higher rates for smaller labs. As a result, including all labs in our sampling frames, regardless of size, could lead to more representative private payer rates when setting the CMS payment rate. However, in both our stratified sampling and MBS, the probability that smaller labs would be selected for our samples are lower relative to larger labs. In addition, even if sampled, the private payer rates of the labs with lower testing volume may not have a significant impact on the CMS payment rate if it is weighted by testing volume.

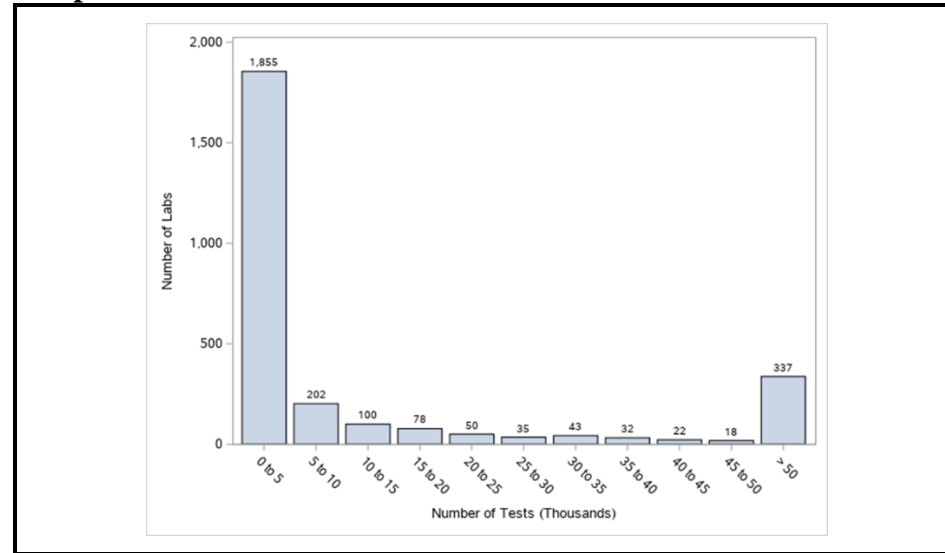
Table 3-4 shows the number of labs that would be included in the sampling frames using CMS's low expenditure threshold of \$12,500 for a 6-month data collection period, or \$25,000 for a calendar year. Only 7,924 labs meet this expenditure threshold, which are only 12.8% of all otherwise eligible labs (including other labs). However, 52% of independent labs and 50% of hospital labs meet the \$25,000 threshold while only 9% of physician office labs meet this threshold.

Figure 3-1. Histograms of Testing Volume by Lab, 2018

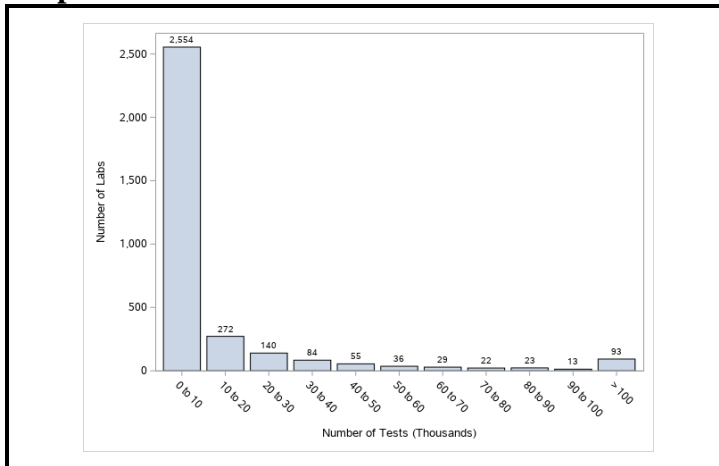
Physician Office Labs



Independent Labs



Hospital Labs



Source: RTI International analysis of 2018 Medicare claims.

RTI program reference: LS5

Table 3-3. Distribution of Testing Volume by Lab, 2018

| Lab type | Number of Labs | Minimum | 25th Percentile | Median | 75th Percentile | Mean | Maximum |
|------------------|----------------|---------|-----------------|--------|-----------------|--------|------------|
| Independent | 2,772 | 1 | 228 | 1,224 | 10,883 | 75,622 | 14,483,476 |
| Hospital | 3,321 | 1 | 406 | 2,018 | 8,724 | 13,825 | 905,411 |
| Physician office | 51,405 | 1 | 21 | 108 | 479 | 1,832 | 1,637,159 |

Source: RTI International analysis of 2018 Medicare claims data and CMS private payer rate data.

RTI program reference: LS5

Table 3-4. Number of Labs Above \$25,000 Payment Threshold, 2018

| Threshold for Labs | Labs Meeting Threshold | | | |
|--------------------|------------------------|-------------|----------|------------------|
| | All* | Independent | Hospital | Physician Office |
| All labs | 61,803 | 2,772 | 3,321 | 51,405 |
| At least \$25,000 | 7,924 | 1,435 | 1,677 | 4,627 |

Source: RTI International analysis of 2018 Medicare claims.

Note: *All labs includes independent, hospital, physician office, and other labs.

RTI program reference: LS3

Table 3-5 further examines the impact of excluding physician office labs with less than \$25,000 payment in 2018. We include the HCPCS code, number of labs with data, the testing volume, and weighted median of price. We report information for the full sampling frame, the restricted frame, and relative difference. The relative difference is the difference between the value in the restricted frame and the full frame divided by the full frame value. The relative differences in weighted median price is small with the largest relative difference for HCPCS code 88262, with a weighted median price difference of about 50%. Because we simulated the prices for each lab using lognormal distributions, the small relative differences between the restricted and full frames are likely driven by the larger labs' testing volume swamping the testing volume of the smaller labs rather than by systematic differences between prices in the full versus restricted frames.

Table 3-5. Comparison of the Full and Restricted Sampling Frames for Physician Office Labs, 2018

| HCPCS Code | Number of Labs with Data | | | Testing Volume | | | Weighted Median Price* |
|--------------|--------------------------|------------------|---------------------|----------------|------------------|---------------------|------------------------|
| | Full Frame | Restricted Frame | Relative Difference | Full Frame | Restricted Frame | Relative Difference | Relative Difference |
| 80053 | 4,941 | 2,508 | -0.492 | 7,847,449 | 7,743,895 | -0.013 | 0.000 |
| 80061 | 6,323 | 2,498 | -0.605 | 5,007,895 | 4,742,274 | -0.053 | -0.007 |
| 82378 | 380 | 338 | -0.111 | 247,232 | 246,962 | -0.001 | 0.000 |
| 83036 | 12,460 | 2,671 | -0.786 | 5,283,829 | 4,063,288 | -0.231 | -0.003 |
| 84445 | 59 | 54 | -0.085 | 673 | 617 | -0.083 | 0.000 |
| 86003 | 214 | 155 | -0.276 | 485,550 | 448,001 | -0.077 | 0.000 |
| 86148 | 20 | 19 | -0.050 | 4,780 | 4,778 | 0.000 | 0.000 |
| 87150 | 22 | 12 | -0.455 | 301 | 280 | -0.070 | 0.000 |
| 87902 | 42 | 33 | -0.214 | 221 | 209 | -0.054 | 0.000 |
| 88262 | 13 | 10 | -0.231 | 1,494 | 1,474 | -0.013 | 0.499 |

Source: RTI International analysis of 2018 Medicare claims and CMS private payer rate data.

Notes: We constructed the restricted frame by only including labs above \$25,000 in payment from the 2018 Medicare claims. Relative difference is the restricted frame value minus the full frame value divided by the full frame value. *Weighted median price is based on prices simulated using the CMS private payer rate data.

Since the restricted frame includes significantly fewer labs compared to the full sampling frame while representing a disproportionate share of the testing volume and relatively small difference in the weighted median price, we apply the \$25,000 threshold to physician office labs in the sampling results section 3.2. However, when evaluating the resulting sample for selected codes, we compare the payment rates from the sample with the payment rates for *all*, not only the physician office labs above the \$25,000 threshold. This allows us to examine if restricting to labs above the threshold negatively affects the accuracy of the payment rate for selected HCPCS codes.

3.1.4 Low-volume Codes

While we include all HCPCS codes with at least one test in our sampling frames, low-volume codes may present challenges to CMS when setting payment rates since the data on which the payment rates would be based may be unreliable. Table 3-6 shows the bottom 20th percentile of HCPCS codes in terms of testing volume using 2018 Medicare claims. We calculated these percentiles after removing the more than 90 codes with 0 testing volume in the 2018 Medicare claims. There are 249 codes in the 20th percentile or below in terms testing

volume, representing 6,671 tests and \$651,360 in payment, or 0.00% of total testing volume in 2018 and 0.01% of total payment. All these codes had 112 or fewer tests billed in 2018. At the extreme, 31 codes are in the 1st percentile with only one test billed in 2018, representing 31 tests and \$11,209 in payment. While some of these tests may have been conducted more by labs for private payers, these tests would be candidates to yield low volume in data collected from surveying labs.

Table 3-6. Testing Volume and Payment for Low-volume HCPCS Codes, 2018

| Percentile by Testing Volume | Percentile | | | Percent of Total Volume for All HCPCS Codes | Total Payment | |
|------------------------------------|-------------------|-----------------|-------------------------------|---|--|-----------------------------------|
| | Testing Volume | At or Below | | | All Codes at or Below Percentile, \$ | Percent for All HCPCS Codes |
| | | Number of Codes | Total Volume for All Codes | | | |
| 1st | 1 | 31 | 31 | 0.00 | 11,209 | 0.00 |
| 5th | 3 | 65 | 108 | 0.00 | 26,400 | 0.00 |
| 10th | 13 | 125 | 536 | 0.00 | 70,944 | 0.00 |
| 15th | 40 | 188 | 2,032 | 0.00 | 235,942 | 0.00 |
| 20th | 112 | 249 | 6,671 | 0.00 | 651,360 | 0.01 |

Source: RTI International analysis of 2018 Medicare claims data.

RTI program reference: LS5

Almost all of the labs who billed these low-volume codes also billed other codes. In other words, few labs only billed these low-volume codes. For example, of the 871 labs that billed codes at or below the 20th percentile, 861 (99%) of these labs also billed other codes. To the extent that the labs who billed low-volume codes were also sampled for other codes, including these low-volume codes may not increase the size of our sample of labs and therefore may not increase the reporting burden.

Nonetheless, Medicare may consider using crosswalking (using existing tests or combination of tests with similar methodology and resources to set payment rates) or gapfilling (Medicare Administrative Contractors develop a payment rate) methodologies that they currently use for codes with 0 testing volume reported in the private payer rate data.

3.2 Sampling

In this section, we discuss the advantages and disadvantages of a census. We also present and discuss our results from our stratified sampling and our MBS sampling methods.

3.2.1 Census

A census requires all labs in our sampling frames to report private payer rate data. Assuming that all labs in our sampling frames report private payer rate data, by definition, a census would result in private payer rates that are representative of the sampling frames. In addition, unlike with sampling, we would not need to estimate margins of errors for private payer rates for each HCPCS code.

However, on the other hand, a census would lead to the maximum reporting burden. Reporting may be especially burdensome for smaller labs that may only bill a handful tests each year. For example, if CMS does not set a relatively high threshold for labs to be included in the sampling frames, a census would require physician office labs with 1-2 physicians to report private payer rate data for the few tests they bill each year. This reporting would be in addition to other reporting required by CMS (e.g., the Quality Payment Program) and other payers. Addressing these types of reporting challenges may be burdensome (Bonislowski, 2019). Stakeholders have estimated that reporting private payer rate data may require significant IT system changes that could cost \$300,000-\$600,000 (Federal Register, 2016). While these concerns and cost estimates are difficult to verify, they do illustrate stakeholders' concerns regarding reporting burden.

If sampling can produce unbiased estimates of private payer rates that are representative of the rates paid to each lab type, this reporting burden may not be necessary. Nonetheless, for our analysis, we regard the census as a benchmark to which we compare results from our sampling methods.

3.2.2 Sample Sizes

Table 3-7 shows the observed sample size for our stratified sampling for our 10 selected HCPCS codes and the expected sample size for MBS for all HCPCS codes. Almost all of the observed sample size for our stratified samples are certainty labs, which include the labs that billed for HCPCS codes with less than the target number of labs for each HCPCS code. For example, if a target number of labs for each HCPCS code is 10 and only five labs billed for HCPCS code 12345, those five labs are certainty labs. The number of certainty labs represent the minimum sample size for either stratified sampling or MBS. Since we only evaluated 10 HCPCS codes, we do not know how much the observed stratified sample size might have increased if we had examined all the HCPCS codes. Consequently, the observed samples sizes for the stratified sampling are only based on the 10 HCPCS codes that we did evaluate and would likely be higher for all HCPCS codes. For MBS, the expected sample size is the sum of the MBS probabilities of

selection and represents the expected sample size for the MBS sample for all HCPCS codes. We also show observed labs for stratified sampling and the expected sample size for MBS as a percent of the labs in the frame. These percentages show how much sampling would reduce the reporting burden compared to a census.

As described in section 2.2, for both stratified sampling and MBS, the first step is to specify the target number of labs for each HCPCS code. Because labs bill more than one HCPCS code, for stratified sampling, prior to completing the sampling process, we cannot calculate the final number of labs that would be sampled for each HCPCS code (see section 2.2.1 for a detailed discussion). As a result, we cannot implement power calculations to inform the choice of targets. However, there is a trade-off between reducing burden by specifying a smaller target versus achieving higher accuracy. For this proof of concept, we decided to start with targets of 10, 20, and 30, since these seemed reasonable values as a start.

For example, for a target number of labs of 10, we sampled 466 independent labs using stratified sampling for the 10 selected HCPCS codes. These 466 labs represented 17% of the 2,772 independent labs in the frame. The expected sample size for MBS with a target number of labs of 10 was 867 independent labs (31% of the 2,772 independent labs in the frame). Compared to a census, which would require all labs in the frame to report, MBS eliminates the reporting burden for 69% of independent labs. The number of observed labs for the stratified sample and the expected sample size for MBS increases as the target sample size increases. For example, for physician office labs, a target sample size of 30 leads to 1,276 labs observed in the stratified sampling (28% of all 4,627 physician office labs in the frame) and 2,305 labs expected for MBS (half of all labs in the frame).

Overall, the observed number of labs for stratified sampling is lower than the expected sample size for MBS. First, the observed number of labs for stratified sampling is only for our 10 selected HCPCS codes and would likely be higher if we calculated them for all HCPCS codes. Second, the observed number of labs for stratified sampling is almost all certainty labs whereas the expected sample size for MBS includes many non-certainty labs. The inclusion of non-certainty labs for MBS leads to less bias when estimating payment rates compared to stratified sampling, as discussed below.

Table 3-7. Observed and Expected Sample Sizes

| Lab Type | Number of | | | Sample Size | | | |
|------------------|-------------------------|--|---|---|--------------------------|------------------|--------------------------|
| | Number of Labs in Frame | Number of HCPCS Codes with at Least One Test | Target Number of Labs for Each HCPCS Code | Observed Number of Labs for Stratified Sampling** | Percent of Labs in Frame | Expected for MBS | Percent of Labs in Frame |
| Independent | 2,772 | 1,197 | 10 | 466 | 17% | 867 | 31% |
| | | | 20 | 681 | 25% | 1,118 | 40% |
| | | | 30 | 844 | 30% | 1,287 | 46% |
| Hospital | 3,321 | 1,105 | 10 | 562 | 17% | 1,139 | 34% |
| | | | 20 | 943 | 28% | 1,572 | 47% |
| | | | 30 | 1,268 | 38% | 1,828 | 55% |
| Physician Office | 4,627* | 1,023 | 10 | 599 | 13% | 1,381 | 30% |
| | | | 20 | 986 | 21% | 1,935 | 42% |
| | | | 30 | 1,276 | 28% | 2,305 | 50% |

Source: RTI International analysis of 2018 Medicare claims data.

Notes: * We restricted physician office labs to those with spending greater than or equal to \$25,000. ** The observed number of labs for stratified sampling only includes labs sampled for our 10 selected HCPCS codes. In contrast, the expected sample size for MBS is for all HCPCS codes.

3.2.3 Evaluation Criteria and Results

The goal of our sampling was to obtain unbiased estimates of each HCPCS code's payment rate that are close to the payment rates in the sampling frames and reduce reporting burden when compared to a census. Consequently, we use empirical bias and sample size as the main criteria for the evaluation. Our primary focus is on the empirical bias, and our secondary focus is on the sample sizes. If sampling produces estimates of the payment rate that are biased, even reductions in reporting burden would not necessarily justify such a sampling method. Table 3-8 shows the empirical bias and the sample sizes for each of the 10 selected HCPCS codes and for independent, hospital, and physician office labs. For each code, we show the number of labs billing each code in the sampling frame and sampling results for stratified sampling and MBS. We also show results for each of the sampling methods using a target sample size of 10 labs per HCPCS code, 20 labs per code, and 30 labs per code. We did not test larger target sample sizes since the empirical bias we find for MBS is already minimal with these target sample sizes. We calculate empirical bias as the difference between the mean payment rate estimate from the sample and the mean payment rate from the sampling frame divided by the mean payment rate

from the sampling frame. We also calculated another measure of empirical bias using the difference between the median payment rate weighted by testing volume from the sample and that from the sampling frame divided by the weight median payment rate from the sampling frame. However, for simplicity, we report the empirical bias using the mean payment rate, which is a common measure of bias, in Table 3-8, but include the empirical bias using the weighted median payment rate in Appendix E. For each type of lab (physician, hospital, independent), we calculated the payment rate for a given HCPCS code from the 10 labs that we selected and compared that to the payment rate for all labs that billed for that HCPCS code, obtained from the sampling frame. For physician office labs, we use the payment rate from the sampling frame using all labs, not just labs over the \$25,000 threshold, as our benchmark to calculate empirical bias. We simulated 1,000 samples for each sampling method and report the mean empirical bias and sample size from these 1,000 samples. We also show a measure of the variation in Appendix E. However, likely because of the large number of certainty labs, the variation is minimal for MBS. For stratified sampling, the sampled labs for almost all of our 10 selected HCPCS codes only included certainty labs. As a result, the payment rate did not vary across our 1,000 samples.

For example, Table 3-8 shows that for HCPCS code 80061, 1,482 independent labs billed for this code in 2018. If we were to conduct a census, we would include all 1,482 labs. With a target sample size of 10 labs for each code, MBS resulted in 563 sampled labs that billed this code (38% of the 1,482 labs that billed for this code) whereas stratified sampling resulted in 325 sampled labs (22% of all labs that billed for this code) that billed this code. As shown by the empirical bias, the payment rate resulting from the 563 sampled labs by MBS is the same as the payment rate from all 1,482 labs that billed for this code. However, the payment rate resulting from the 325 sampled labs from stratified sampling is 1.3% lower than the payment rate from all 1,482 labs that billed for this code. The number of sampled labs for both MBS and stratified sampling increases with target sample sizes of 20 and 30 labs. In addition, with larger sample sizes, while the empirical bias for MBS stays the same, the empirical bias for stratified sampling decreases. With a target sample size of 30 labs, the payment rate resulting from the 605 sampled labs is 0.7% lower than the payment rate from all labs that billed for this code.

As another example, Table 3-8 shows that for HCPCS code 80053, 2,508 physician office labs billed for this code in 2018. With a target sample size of 10 labs for each code, MBS resulted in 957 sampled labs that billed this code (38% of the 2,508 labs that billed for this code) whereas stratified sampling resulted in 469 sampled labs (19% of all labs that billed for this code) that billed this code. Like 80061, the empirical bias shows that the payment rate resulting from the 957 sampled labs by MBS is the same as the payment rate from all 2,508 labs that billed

for this code. However, the payment rate resulting from the 469 sampled labs from stratified sampling is 95.2% higher than the payment rate from all 2,508 labs that billed for this code. This large empirical bias is likely because these 469 sampled labs are all certainty labs, which are labs that were included in our sample because they billed for codes with fewer than 10 labs (the target sample size). As a result, for stratified sampling, we did not randomly select among the 2,508 labs that billed for 80053, which is likely to lead to biased results. The number of sampled labs for both MBS and stratified sampling increases with target sample sizes of 20 and 30 labs. However, the empirical bias for stratified sampling decreases with larger target sample sizes.

In addition, Table 3-8 shows that for some codes, increases in target sample sizes actually led to *increases* in empirical bias for stratified sampling. For example, for 86003, the empirical bias with a target sample size of 10 indicated the payment rate from the 175 sampled independent labs was 0.7% higher than the payment rate from all 327 labs that billed this code whereas the empirical bias with a target sample size of 20 indicated an 8.2% lower payment rate than the payment rate for all labs that billed this code. This is a result of a different set of certainty labs with a target sample size of 20. Because certainty labs do not represent a random sample of all labs that billed this code, a larger set of certainty labs may result in larger empirical bias. Larger samples can create more biased estimates, if the additional sample is more biased.

Finally, for physician office labs, three codes (i.e., 86148, 87150, and 88262) were billed by less than 20 labs. As a result, for target sample sizes of 20 and 30 (and even 10 for 88262), all labs that billed these codes were included in both stratified sampling and MBS. These labs are considered certainty labs with empirical biases for both stratified and MBS of 0.

For more detailed sampling results, please see Appendix E, which also includes results for the number of non-certainty labs in the sampling frame, the absolute value of the empirical bias, the empirical bias calculated using the weighted median price, the standard error as a measure of variation, the proportion of samples that include the benchmark payment rate in the 95% confidence interval of the sample (i.e., the mean minus two times the standard error through the mean plus two times the standard error), and the proportion of the testing volume included in the sample.

Table 3-8. Empirical Bias and Samples Sizes for Selected HCPCS Codes by Lab Type

| | Target Sample (minimum number of labs) | | | | | |
|-------------------------------------|--|------------|---------|------------|---------|------------|
| | Size 10 | | Size 20 | | Size 30 | |
| | MBS | Stratified | MBS | Stratified | MBS | Stratified |
| Independent Labs | | | | | | |
| 80053 (1,636 labs with data) | | | | | | |
| Number of Labs in Sample | 569 | 322 | 737 | 487 | 851 | 606 |
| Empirical Bias | 0.000 | -0.006 | 0.000 | -0.004 | 0.000 | -0.004 |
| 80061 (1,482 labs with data) | | | | | | |
| Number of Labs in Sample | 563 | 325 | 724 | 490 | 831 | 605 |
| Empirical Bias | 0.000 | -0.013 | 0.000 | -0.010 | 0.000 | -0.007 |
| 82378 (842 labs with data) | | | | | | |
| Number of Labs in Sample | 408 | 256 | 510 | 376 | 574 | 451 |
| Empirical Bias | 0.000 | 0.000 | 0.000 | 0.006 | 0.000 | 0.003 |
| 83036 (1,491 labs with data) | | | | | | |
| Number of Labs in Sample | 560 | 322 | 721 | 486 | 826 | 602 |
| Empirical Bias | 0.000 | 0.008 | 0.000 | -0.002 | 0.000 | -0.005 |
| 84445 (232 labs with data) | | | | | | |
| Number of Labs in Sample | 197 | 150 | 214 | 191 | 222 | 212 |
| Empirical Bias | 0.000 | -0.005 | 0.000 | -0.002 | 0.000 | -0.001 |
| 86003 (327 labs with data) | | | | | | |
| Number of Labs in Sample | 249 | 175 | 277 | 232 | 290 | 258 |
| Empirical Bias | 0.000 | 0.007 | 0.000 | -0.082 | 0.000 | -0.068 |
| 86148 (133 labs with data) | | | | | | |
| Number of Labs in Sample | 121 | 96 | 127 | 116 | 130 | 123 |
| Empirical Bias | 0.000 | 0.168 | 0.000 | 0.303 | 0.000 | 0.301 |
| 87150 (88 labs with data) | | | | | | |
| Number of Labs in Sample | 80 | 61 | 84 | 75 | 87 | 78 |
| Empirical Bias | 0.000 | 0.194 | 0.000 | 0.207 | 0.000 | 0.169 |
| 87902 (241 labs with data) | | | | | | |
| Number of Labs in Sample | 202 | 148 | 219 | 193 | 228 | 212 |
| Empirical Bias | 0.000 | -0.004 | 0.000 | 0.000 | 0.000 | 0.000 |
| 88262 (83 labs with data) | | | | | | |
| Number of Labs in Sample | 77 | 68 | 80 | 73 | 82 | 75 |
| Empirical Bias | 0.001 | -0.047 | 0.000 | 0.004 | 0.000 | 0.005 |

(continued)

**Table 3-8. Empirical Bias and Samples Sizes for Selected HCPCS Codes by Lab Type
(continued)**

| | Target Sample | | | | | |
|-------------------------------------|---------------|------------|---------|------------|---------|------------|
| | Size 10 | | Size 20 | | Size 30 | |
| | MBS | Stratified | MBS | Stratified | MBS | Stratified |
| Hospital Labs | | | | | | |
| 80053 (3,049 labs with data) | | | | | | |
| Number of Labs in Sample | 1,112 | 549 | 1,534 | 923 | 1,780 | 1,244 |
| Empirical Bias | -0.002 | 0.045 | 0.001 | 0.021 | 0.000 | 0.010 |
| 80061 (2,836 labs with data) | | | | | | |
| Number of Labs in Sample | 1,093 | 541 | 1,503 | 904 | 1,744 | 1,216 |
| Empirical Bias | -0.001 | 0.006 | 0.000 | -0.008 | 0.000 | 0.021 |
| 82378 (1,405 labs with data) | | | | | | |
| Number of Labs in Sample | 786 | 422 | 1,021 | 666 | 1,136 | 861 |
| Empirical Bias | 0.002 | -0.072 | -0.001 | -0.074 | 0.000 | -0.056 |
| 83036 (2,824 labs with data) | | | | | | |
| Number of Labs in Sample | 1,096 | 544 | 1,506 | 910 | 1,744 | 1,223 |
| Empirical Bias | -0.001 | 0.017 | 0.000 | 0.014 | 0.000 | 0.004 |
| 84445 (579 labs with data) | | | | | | |
| Number of Labs in Sample | 422 | 266 | 502 | 381 | 533 | 451 |
| Empirical Bias | 0.000 | 0.009 | 0.000 | 0.014 | 0.000 | 0.010 |
| 86003 (749 labs with data) | | | | | | |
| Number of Labs in Sample | 520 | 309 | 624 | 464 | 670 | 573 |
| Empirical Bias | 0.000 | -0.003 | 0.000 | -0.003 | 0.000 | 0.000 |
| 86148 (146 labs with data) | | | | | | |
| Number of Labs in Sample | 116 | 84 | 136 | 112 | 141 | 124 |
| Empirical Bias | 0.001 | 0.053 | 0.000 | 0.015 | 0.000 | 0.002 |
| 87150 (240 labs with data) | | | | | | |
| Number of Labs in Sample | 160 | 94 | 194 | 142 | 214 | 177 |
| Empirical Bias | -0.001 | 0.018 | 0.000 | 0.003 | 0.000 | 0.003 |
| 87902 (651 labs with data) | | | | | | |
| Number of Labs in Sample | 482 | 292 | 571 | 436 | 605 | 522 |
| Empirical Bias | 0.000 | 0.018 | 0.001 | 0.020 | 0.000 | 0.012 |
| 88262 (86 labs with data) | | | | | | |
| Number of Labs in Sample | 70 | 56 | 78 | 67 | 82 | 72 |
| Empirical Bias | 0.000 | -0.028 | 0.001 | 0.016 | 0.000 | 0.010 |

(continued)

**Table 3-8. Empirical Bias and Samples Sizes for Selected HCPCS Codes by Lab Type
(continued)**

| | Target Sample | | | | | |
|-------------------------------------|---------------|------------|---------|------------|---------|------------|
| | Size 10 | | Size 20 | | Size 30 | |
| | MBS | Stratified | MBS | Stratified | MBS | Stratified |
| Physician Office Labs | | | | | | |
| 80053 (2,508 labs with data) | | | | | | |
| Number of Labs in Sample | 957 | 469 | 1,303 | 743 | 1,523 | 951 |
| Empirical Bias | 0.000 | 0.952 | 0.000 | 0.471 | 0.002 | 0.300 |
| 80061 (2,498 labs with data) | | | | | | |
| Number of Labs in Sample | 947 | 469 | 1,291 | 745 | 1,508 | 953 |
| Empirical Bias | -0.004 | -0.071 | -0.001 | -0.065 | -0.001 | -0.088 |
| 82378 (338 labs with data) | | | | | | |
| Number of Labs in Sample | 206 | 122 | 254 | 165 | 278 | 196 |
| Empirical Bias | 0.001 | -0.126 | -0.001 | -0.067 | -0.002 | -0.030 |
| 83036 (2,671 labs with data) | | | | | | |
| Number of Labs in Sample | 934 | 460 | 1,289 | 738 | 1,520 | 949 |
| Empirical Bias | -0.002 | -0.131 | -0.002 | 0.112 | 0.003 | 0.067 |
| 84445 (54 labs with data) | | | | | | |
| Number of Labs in Sample | 44 | 33 | 47 | 42 | 51 | 47 |
| Empirical Bias | 0.000 | 0.130 | 0.000 | 0.026 | 0.000 | 0.007 |
| 86003 (155 labs with data) | | | | | | |
| Number of Labs in Sample | 107 | 69 | 124 | 85 | 138 | 99 |
| Empirical Bias | -0.018 | 0.563 | -0.003 | 0.334 | 0.001 | -0.214 |
| 86148 (19 labs with data) | | | | | | |
| Number of Labs in Sample | 18 | 16 | 19 | 19 | 19 | 19 |
| Empirical Bias | 0.000 | 0.094 | 0.000 | 0.000 | 0.000 | 0.000 |
| 87150 (12 labs with data) | | | | | | |
| Number of Labs in Sample | 11 | 10 | 12 | 12 | 12 | 12 |
| Empirical Bias | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| 87902 (33 labs with data) | | | | | | |
| Number of Labs in Sample | 30 | 28 | 32 | 31 | 33 | 32 |
| Empirical Bias | 0.000 | -0.008 | 0.000 | -0.011 | 0.000 | -0.006 |
| 88262 (10 labs with data) | | | | | | |
| Number of Labs in Sample | 10 | 10 | 10 | 10 | 10 | 10 |
| Empirical Bias | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |

Source: RTI International analysis of 2018 Medicare claims and CMS private payer rate data.

We find two consistent patterns across the 10 HCPCS codes and 3 target sample sizes:

- The empirical bias for MBS is much closer to zero than stratified sampling. For example, for independent labs billing 86148, the empirical bias was 0 for MBS and much higher for stratified sampling at a target sample size of 10 labs per HCPCS code. The payment rate estimated by MBS would be about the same as the payment rate in the sampling frame while the payment rate estimated by stratified sampling would be more than 16.8% off.
 - We find similar results using the weighted median payment rate to calculate empirical bias. While there are a handful of HCPCS codes in which stratified sampling resulted in lower bias than MBS, the bias using the weighted median for other codes increased significantly for stratified sampling as compared to the bias using the mean payment rate (see Appendix E for more details). For example, for hospital labs billing 87902, the empirical bias using the weighted median for MBS was 0.7% off while the empirical bias for stratified sampling was 0. In contrast, the empirical bias using the mean for MBS was 0 and 1.8% for stratified sampling. However, in another example, for a target sample size of 10 and independent labs billing 86148, the empirical bias using the weighted median from stratified sampling was 76.3% off while the empirical bias using the mean was 16.8% off.
- The overall sample size for stratified sampling is smaller than that of MBS. For example, for 80053, the sample size for MBS would be 1,112 labs, more than twice that of stratified sampling at 549 labs. Recall that the observed sample size for stratified sampling is only based on the 10 HCPCS codes that were evaluated.

For stratified sampling, virtually all the labs would be selected with certainty for the 10 selected HCPCS codes at target sample sizes of 10, 20 and 30. The only exception was 87150 with a target sample size of 10 for physician office labs. In the method we implemented for stratified sampling, we started with HCPCS codes with fewer labs than the target sample size. Once we completed sampling these certainty labs, we were able to obtain the target sample size for all 10 selected HCPCS codes. As a result, almost all of our sample for these 10 selected HCPCS codes were determined by codes billed by only a few labs and not by random selection. In other words, the certainty labs were not random samples of labs billing these 10 selected HCPCS codes and therefore were generally not representative. This generally led to higher empirical bias as compared with MBS. In addition, for almost all the stratified samples, there was no variation in the payment rates from the 1,000 samples that we simulated. Prior to our analysis, we were expecting more non-certainty labs to be selected for these 10 HCPCS code so that the sample would be approximately unbiased, and we would be able to calculate estimated variances. Further research would include modifying the stratified sampling method we used to include at least two randomly selected labs for each HCPCS code. This modification would increase the sample size for stratified sampling.

Challenges to sampling process

The main challenges we encountered were 1) constructing the sampling frames; and 2) sampling for the almost 1,300 HCPCS codes with some testing volume in 2018. For the first challenge, an example is that we had to decide how to define the universe of lab tests. For example, we decided to exclude claims for hospital lab tests billed for patients in the inpatient and outpatient settings. Eliminating these claims substantially reduced the hospital data used for this analysis. However, this allowed our sampling frame to more closely match what CMS will use in their next round of reporting and more accurately reflect the types of tests that would eventually be paid through the CLFS.

Second, we used CMS's private payer rate data from 2016 to simulate private payer rates for labs in the 2018 Medicare claims data so that we can compare the payment rates obtained from the sample with the rates from the population. This approach introduces some inherent error. To the extent that the distribution of private payer rates in 2016 differs from the rates in 2018, private payer rates for 2018 that was simulated using 2016 data would be unreliable. As a result, it would be difficult to accurately assess whether the 2018 sample is representative of all labs in 2018. For example, if a large number of labs that billed HCPCS code 12345 opened between 2016 and 2018 with these new labs having lower payment rates than the 2016 labs, any distribution of private payer rates from the 2016 private payer rate data would be unreliable for simulating private payer rates for HCPCS code 12345 for 2018. This challenge would apply for any future survey. Past data cannot be used to perfectly examine whether the future survey would lead to representative results. As a result, there would always be uncertainty as to whether the survey would lead to private payer rates that would be representative of all labs.

Third, there are almost 1,300 HCPCS codes with some testing volume in 2018. Because of the number of HCPCS codes, reviewing the sampling results is challenging due to the amount of resources and time required. For example, if there were only a few different HCPCS codes, we could examine the sampling results for each code to make sure that we calculated unbiased estimates of the private payer rates for each lab type. However, with almost 1,300 different tests, we can only focus on a few select HCPCS codes, as we did in this report. It would be difficult to make sure we obtained a reasonable sample for all HCPCS codes.

Lab non-response may present another set of challenges when implementing these sampling strategies. High levels of non-response increase the potential for nonresponse bias, i.e., a greater chance that the estimates will be biased and not be representative of all labs. For example, large labs that have invested in health information technology systems or with administrative staff available to prepare information on private payer rates are more likely to

report. However, CMS may consider the following activities to help maximize the response rates and minimize the effect of nonresponse: increasing outreach to labs both before and during the survey period, creating incentives for labs to respond, proactively oversampling to account for non-response, conducting non-response bias analysis, and implementing post-data collection weight adjustments and/or calibration for non-response.

3.2.4 *Description of Hypothetical Data Analysis and Reporting*

After sampling, we would implement the following steps to analyze the data and report results. First, we would assess the data we collected for quality, and, if necessary, edit the data to ensure reasonable and usable data (e.g., for a specific HCPCS code, if one lab reports a private payer rate of \$780.00 but all other labs report a rate of \$7.80, CMS should further examine the data from the lab reporting the rate of \$780.00 to determine if the lab had made a typo).

Second, we would use appropriate software, such as SUDAAN® Statistical Software for Weighting, Imputing, and Analyzing Data (RTI, 2012), to account for the complex sampling method, whether stratified sampling or MBS, and differential weighting in calculating valid point estimates and standard errors. We would compare collected data to CMS's Round 1 of private payer data or to the 2017 national limitation amount to assess validity. This comparison would be useful to validate the next round of sampling, but would likely reflect the market less accurately as more time passed. We would also assess the reliability by examining the magnitude of the standard errors.

Since we constructed separate sampling frames for each lab type, we would produce private payer rates estimates for each HCPCS code and separately for independent, hospital, and physician office labs. For each HCPCS code, we would also calculate a combined estimate of the private payer rate, potentially weighted by testing volume from each lab type.

In addition, our separate sampling frame for different lab types affords us the option of sampling some lab types while conducting a census of others. For example, we could combine private payer rate estimates derived from sampling physician office labs with data reported from a census of independent and hospital labs to generate combined payment rates. However, this relies on the assumption that data reported from independent and hospital labs are not limited by selection bias (i.e., if the private payer rates of reporting labs are systematically different from the private payer rates of labs not reporting). Sampling physician office labs would enable CMS to reduce the number of physician office labs required to report, while maintaining robust estimates of independent and hospital lab prices through a census, if desired.

Finally, we would use a ratio procedure in SUDAAN to improve the estimates for private payer rates for each HCPCS code. The ratio would be the weighted sum of the total payment for the HCPCS code divided by the weighted sum of the number of tests for the HCPCS code. The ratio procedure in SUDAAN is specifically designed for situations where both the numerator and denominator in the ratio calculation are random variables, which is the situation we have here. Neither the numerator nor denominator are fixed values. Their values depend on the specific sample selected. Selecting a different sample could produce different estimates.

SECTION 4.

CONCLUSION

4.1 Summary of Results

We used 2018 Medicare claims data to construct sampling frames including all labs that were paid through the CLFS in 2018. We used the billing NPI on the claim to define a lab and categorized each lab into either independent, hospital, physician office, or other labs. We constructed separate sampling frames for each main lab type so that our resulting sampling is representative of each lab type. This helps to address the main criticism of CMS's approach in the first round of reporting private lab payment rates, which was that the labs reporting private payer rates were disproportionately independent labs. Very few hospital labs reported data and physician office labs were substantially underrepresented. As a result, the reported data was not representative of all labs.

We used two sampling methods: stratified sampling and MBS. To evaluate these two sampling methods, we selected 10 HCPCS codes to compare the results of sampling with a census. These 10 HCPCS codes included three of the five top codes in terms of testing volume in 2018 and codes with large differences between the weighted median price for independent and hospital labs and between independent and physician office labs. First, by lab type, we compared the payment rates for these 10 codes from each sampling method with that of the sampling frame, based on payment rates from CMS's private payer rate data. Second, we compared the resulting sample sizes. We found that MBS produced estimated payment rates that were much closer to the true payment rates from the sampling frame compared to stratified sampling. In addition, compared to a census, both sampling methods resulted in significantly fewer labs that would be required to report private payer rate data. For example, of the 4,627 physician office labs above \$25,000 in spending for 2018, only 1,381 labs (30% of all labs above \$25,000) were sampled using MBS for all HCPCS codes using a target sample size of 10 labs. MBS would ease the reporting burden significantly, without sacrificing the ability to obtain estimates of payment rates that are unbiased and representative of each lab type. While stratified sampling would also ease the reporting burden of a census, we found that, for our 10 selected HCPCS codes, stratified sampling generally led to larger differences between the estimated payment rates from the sampled labs and that of the true payment rates from the entire sampling frame. Since differences between the estimated payment rates from the sampled labs and that of the true payment rates from the entire sampling frame is our first evaluation criteria for these sampling methods, these differences for stratified sampling outweighs the reduction in reporting burden. If a sampling

method leads to such differences, reductions in reporting burden may not be worth obtaining biased payment rates, especially if MBS does not result in such differences.

4.2 Limitations

We were only able to evaluate the empirical bias for both stratified sampling and MBS for 10 selected HCPCS codes. While we were able to calculate the expected sample sizes for all HCPCS codes for MBS, we were not able to calculate sample sizes for all HCPCS codes for stratified sampling. While these selected HCPCS codes are illustrative, they cannot be generalizable to all CLFS HCPCS codes. We were restricted in our ability to examine all CLFS HCPCS codes due to resource and time constraints. Nonetheless, we did evaluate the empirical bias of sampling methods for three of the top five HCPCS codes by testing volume in 2018 and some codes with significant differences in weighted median price across lab types.

Following CMS, we defined labs using the NPI on the Medicare claim and did not define labs by the lab's Taxpayer Identification Number (TIN). In addition, we were not able to group NPIs into larger lab organizations. While this would not affect our sampling methods, the final sample sizes we estimate represent over-estimates of the number of larger lab organizations would have to report private payer rate data. For example, assuming reporting includes some significant fixed costs, if 10 NPIs that were sampled belonged to one large lab organization, the reporting burden for this one lab organization would likely be less than if these 10 NPIs represented 10 unique lab organizations each having to incur any fixed costs associated with reporting.

4.3 Recommendations

Based on our findings, we believe it is feasible for CMS to collect a representative sample of private payer rates to set accurate lab payment rates. Among the two methods we examined, MBS produced unbiased estimates of payment rates, and were less biased than stratified sampling. MBS also substantially reduced reporting burden on labs.

In addition, based on our experience with applying both sampling methods to sampling labs, MBS is easier to implement. Stratified sampling is generally applied in situations where each lab would conduct a unique test and not a variety of tests. For our analysis, we had to design and implement an algorithm for stratified sampling to account for the structure of the lab market. Our algorithm assumed that certainty labs would provide data on all HCPCS codes for which they have data, but labs selected in the probability part of the sample would only provide information for the HCPCS code for which they are sampled. If the labs selected in the probability part of the sample provided information for all HCPCS codes, it would require a

more complicated and dynamic process that depends on the order of the HCPCS codes and which labs get selected for each HCPCS code. In contrast, MBS is designed for situations like lab testing with multiple HCPCS codes where estimates for each HCPCS code is required.

For these reasons, we believe MBS is likely preferable to stratified sampling. However, while this report demonstrates the feasibility of using MBS to estimate lab payment rates, more work is needed to expand this proof of concept to definitively show that this methodology can be used to generate representative payment rates for all CLFS HCPCS codes.

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APPENDIX A:
CLFS HCPCS CODES WITH NO CLAIMS, 2018

| HCPCS Code | Description | HCPCS Code | Description |
|-----------------------|------------------------------|-----------------------|------------------------------|
| 0002U | Onc clrct 3 ur metab alg plp | 81426 | Genome sequence analysis |
| 0003U | Onc ovar 5 prtn ser alg scor | 81427 | Genome re-evaluation |
| 0004M | Scoliosis dna alys | 81430 | Hearing loss sequence analys |
| 0006M | Onc hep gene risk classifier | 81431 | Hearing loss dup/del analys |
| 0007M | Onc gastro 51 gene nomogram | 81438 | Heredtry nurondcrn tum dsrdr |
| 0007U | Rx test prsmv ur w/def conf | 81470 | X-linked intellectual dblt |
| 0009M | Fetal aneuploidy trisom risk | 81471 | X-linked intellectual dblt |
| 0009U | Onc brst ca erbb2 amp/nonamp | 81504 | Oncology tissue of origin |
| 0010U | Nfct ds strn typ whl gen seq | 81506 | Endo assay seven anal |
| 0012U | Germln do gene reargmt detcj | 81510 | Ftl cgen abnor three anal |
| 0013U | Onc sld org neo gene reargmt | 81535 | Oncology gynecologic |
| 0014U | Hem hmtlmf neo gene reargmt | 81536 | Oncology gynecologic |
| 0017U | Onc hmtlmf neo jak2 mut dna | 82776 | Galactose transferase test |
| 80406 | Acth stimulation panel | 83662 | Foam stability fetal lung |
| 80416 | Renin stimulation panel | 83775 | Assay malate dehydrogenase |
| 80426 | Gonadotropin hormone panel | 83857 | Assay of methemalbumin |
| 80434 | Insulin tolerance panel | 84085 | Assay of rbc pg6d enzyme |
| 80436 | Metyrapone panel | 84577 | Assay of feces/urobilinogen |
| 80439 | Trh stimulation panel | 84583 | Assay of urine urobilinogen |
| 81106 | Hpa-2 genotyping | 85170 | Blood clot retraction |
| 81107 | Hpa-3 genotyping | 85337 | Thrombomodulin |
| 81108 | Hpa-4 genotyping | 85400 | Fibrinolytic plasmin |
| 81109 | Hpa-5 genotyping | 85530 | Heparin-protamine tolerance |
| 81111 | Hpa-9 genotyping | 85547 | Rbc mechanical fragility |
| 81112 | Hpa-15 genotyping | 86821 | Lymphocyte culture mixed |
| 81224 | Cftr gene intron poly t | 87003 | Small animal inoculation |
| 81248 | G6pd known familial variant | 87267 | Enterovirus antibody dfa |
| 81249 | G6pd full gene sequence | 87472 | Bartonella dna quant |
| 81253 | Gjb2 gene known fam variants | 87475 | Lyme dis dna dir probe |
| 81258 | Hba1/hba2 gene fam vrnt | 87526 | Hepatitis g dna amp probe |
| 81266 | Str markers spec anal addl | 87531 | Hhv-6 dna dir probe |
| 81280 | Long qt synd gene full seq | 87534 | Hiv-1 dna dir probe |
| 81281 | Long qt synd known fam var | 87537 | Hiv-2 dna dir probe |
| 81282 | Long qt syn gene dup/dlt var | 87562 | M.avium-intra dna quant |
| 81302 | Mecp2 gene full seq | 87582 | M.pneumon dna quant |
| 81303 | Mecp2 gene known variant | 88140 | Sex chromatin identification |
| 81304 | Mecp2 gene dup/delet variant | 88152 | Cytopath c/v auto redo |
| 81326 | Pmp22 gene known fam variant | 88166 | Cytopath tbs c/v auto redo |
| 81362 | Hbb gene known fam variant | 88167 | Cytopath tbs c/v select |
| 81414 | Car ion chnnlpath inc 2 gns | 88371 | Protein western blot tissue |
| 81417 | Exome re-evaluation | 89329 | Sperm evaluation test |
| 81425 | Genome sequence analysis | 89330 | Evaluation cervical mucus |

| HCPCS Code | Description |
|-----------------------|------------------------------|
| G9143 | Warfarin respon genetic test |
| P2028 | Cephalin flocculation test |
| P2029 | Congo red blood test |
| P2031 | Hair analysis |

| HCPCS Code | Description |
|-----------------------|-------------------------|
| P2033 | Blood thymol turbidity |
| P2038 | Blood mucoprotein |
| Q0115 | Post-coital mucous exam |

Source: RTI International analysis of 2018 Medicare claims data.

RTI program reference: LS5

APPENDIX B:
HCPCS CODES FOR SPECIMEN COLLECTION, TRAVEL ALLOWANCES, AND
UNLISTED LAB CODES EXCLUDED FROM OUR ANALYSIS

| HCPCS Code | Type | Description |
|-------------------|---------------------|------------------------------|
| 36410 | Specimen Collection | Non-routine bl draw 3/> yrs |
| 36415 | Specimen Collection | Routine venipuncture |
| 78267 | Specimen Collection | Breath tst attain/anal c-14 |
| G0471 | Specimen Collection | Ven blood coll snf/hha |
| P9612 | Specimen Collection | Catheterize for urine spec |
| P9615 | Specimen Collection | Urine specimen collect mult |
| P9603 | Travel Allowances | One-way allow prorated miles |
| P9604 | Travel Allowances | One-way allow prorated trip |
| 81099 | Unlisted Lab Code | Urinalysis test procedure |
| 81479 | Unlisted Lab Code | Unlisted molecular pathology |
| 81599 | Unlisted Lab Code | Unlisted maaa |
| 84999 | Unlisted Lab Code | Clinical chemistry test |
| 85999 | Unlisted Lab Code | Hematology procedure |
| 86486 | Unlisted Lab Code | Skin test nos antigen |
| 86849 | Unlisted Lab Code | Immunology procedure |
| 86999 | Unlisted Lab Code | Transfusion procedure |
| 87999 | Unlisted Lab Code | Microbiology procedure |
| 88099 | Unlisted Lab Code | Necropsy (autopsy) procedure |
| 88199 | Unlisted Lab Code | Cytopathology procedure |
| 88299 | Unlisted Lab Code | Cytogenetic study |
| 88399 | Unlisted Lab Code | Surgical pathology procedure |
| 88749 | Unlisted Lab Code | In vivo lab service |
| 89240 | Unlisted Lab Code | Pathology lab procedure |
| 89398 | Unlisted Lab Code | Unlisted reprod med lab proc |

Source: MedPAC

APPENDIX C:
INCLUSION CRITERIA FOR OUTPATIENT CLAIMS FOR CLFS HCPCS CODES
NOT PAID THROUGH THE CLFS

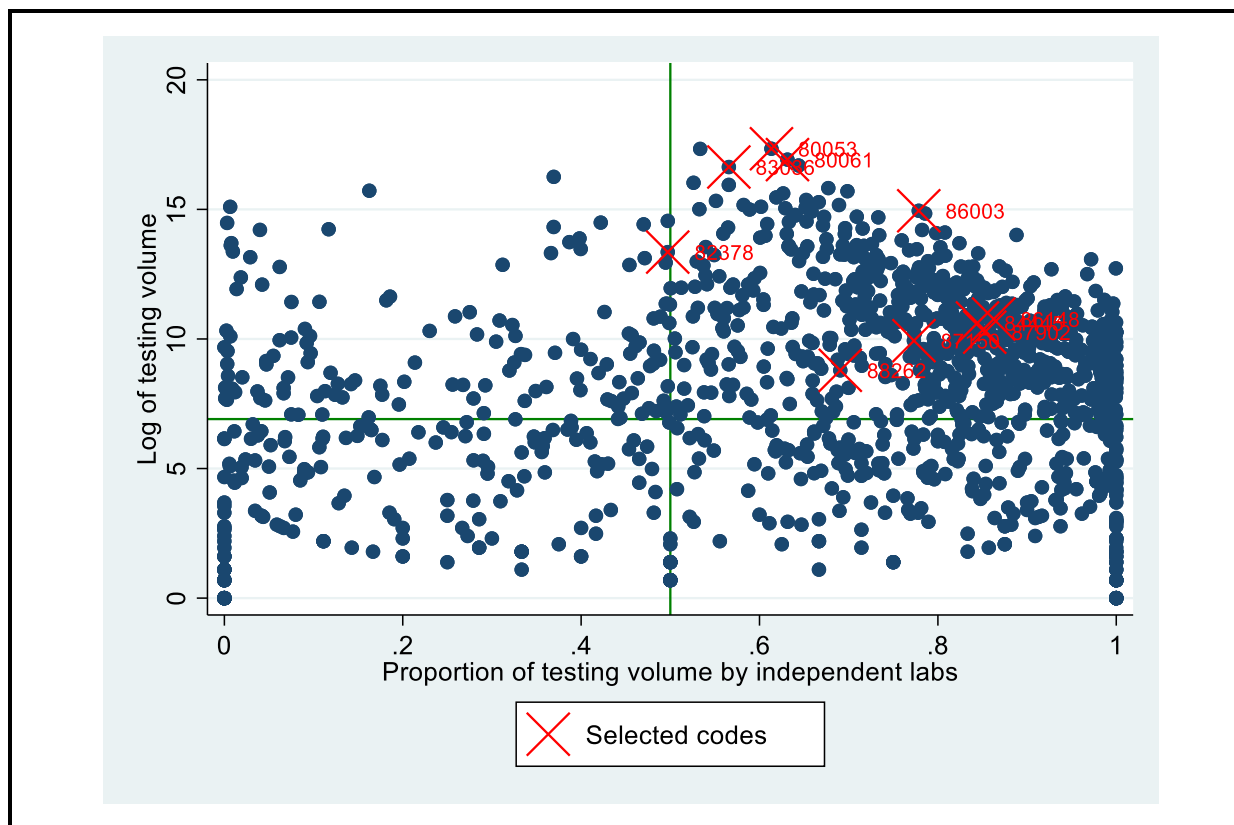
| Type of Bill | Description | OPPS Status Indicator | Modifier | Notes |
|---------------------|---------------------------|------------------------------|-----------------|---|
| 12x | Hospital Inpatient Part B | A | | |
| 13x | Hospital Outpatient | A | | |
| 14x | Hospital outreach | A | | |
| 22x | SNF Inpatient Part B | A, N, and Q1 | | SNFs are paid through SN PPS, so the OPPS status indicators may not necessarily apply. A, N, and Q1 were an exhaustive list of TOBs in the year examined. |
| 23x | SNF Outpatient | A, N, and Q1 | | |
| 72x | ESRD | Any | AY | Unrelated lab services are separately payable and can be billed by the ESRD facility on TOB 72x (must include modifier AY to indicate the lab service was unrelated to ESRD). Not clear that ESRD claims follow the OPPS status indicators for payment. Separately payable lab services are simply identified with modifier “AY.” |

Source: MedPAC analysis of Medicare claims.

APPENDIX D: COMPARING SELECTED HCPCS CODES WITH OTHER CLFS HCPCS CODES

Figure D-1 graphically depicts how the 10 selected codes compare with the other CLFS HCPCS codes with nonzero testing volume in terms of testing volume and proportion of testing volume billed by independent labs. The y-axis is the log of testing volume in Medicare for 2018 and the x-axis is the proportion of testing volume billed by independent labs in Medicare for 2018. All of the codes we selected were above 1,000 tests billed in 2018 and three of the codes were in the top 5 in testing volume. In addition, all codes had at least half of their testing volume billed by independent labs, with three codes (84445, 86148, and 87902) having more than 80% of their testing volume billed by independent labs.

Figure D-1. Scatter Plot of Log of Testing Volume and Proportion of Testing Volume Billed by Independent Labs, by Code in 2018



Source: RTI International analysis of 2018 Medicare claims.

Notes: The horizontal reference line is 1,000 tests billed in 2018 and the vertical reference line is half of testing volume billed by independent labs.

APPENDIX E:

FULL SAMPLING RESULTS FOR SELECTED HCPCS CODES

The tables below show our full sampling results for our 10 selected HCPCS codes. For each code, we show the number of labs billing each code in the sampling frame and sampling results for stratified sampling and MBS, which include the number of non-certainty labs. We also show results for each of the sampling methods using a target sample size of 10 labs per HCPCS code, 20 labs per code, and 30 labs per code. We calculate three measures of empirical bias. The first is the difference between the mean payment rate estimate from the sample and the mean payment rate from the sampling frame divided by the mean payment rate from the sampling frame. The second is the absolute value of the empirical bias using the mean payment rate. And the third is the empirical bias using the median payment rate weighted by testing volume. We simulated 1,000 samples for each sampling method and report the mean empirical bias and sample size from these 1,000 samples. The relative standard error is the standard error from the sample divided by the mean payment rate estimate from the sample. Please see section 2.2.5 for our methodology for calculating the sample variance. Coverage is the proportion of samples that include the benchmark payment rate in the 95% confidence interval of the sample. For physician office labs, we use the payment rate from the sampling frame using all labs, not just labs over the \$25,000 threshold, as our benchmark to calculate empirical bias. For almost all cases, our stratified sampling did not result in any non-certainty labs. As a result, there was no relative standard error or coverage. The only exception was 87150 with a target sample size of 10 for physician office labs.

For example, the tables below show that for HCPCS code 80061, 1,482 independent labs billed for this code in 2018. If we were to conduct a census, we would include all 1,482 labs. With a target sample size of 10 labs for each code, MBS resulted in 563 sampled labs that billed this code (38% of the 1,482 labs that billed for this code) whereas stratified sampling resulted in 325 sampled labs (22% of all labs that billed for this code) that billed this code. MBS also included 112 labs that were non-certainty labs whereas stratified sampling only included certainty labs. For empirical bias, the mean payment rate resulting from the 563 sampled labs by MBS is the same as the mean payment rate from all 1,482 labs that billed for this code. However, the mean payment rate resulting from the 325 sampled labs from stratified sampling is 1.3% lower than the mean payment rate from all 1,482 labs that billed for this code. The median payment rate weighted by testing volume from the MBS sample was 0.7% lower than the median from all labs that billed this code. For stratified sampling, the median was 4.9% lower. The absolute value of the empirical bias using the mean was 0.6% for MBS and 1.3% for stratified

sampling. In terms of variation, the relative standard error for MBS was effectively 0. This is likely due to the large number of certainty labs. Since the resulting sample from stratified sampling consisted only of certainty labs, we could not calculate a relative standard error since there was no variation across different simulations. Because the standard error was effectively 0, the coverage (the proportion of samples that include the benchmark payment rate in the 95% confidence interval of the sample) was only 10.7%, meaning that out of 1,000 simulated samples, only 107 included the benchmark payment rate in the 95% confidence interval. However, since the standard error is so small, this is not surprising and also not a particularly useful measure, but we include our results on coverage for completeness. Finally, the 563 MBS sampled labs represented 96.5% of all testing volume for this code and the 325 labs sampled using stratified sampling represented 87.6%.

The number of sampled labs for both MBS and stratified sampling increases with target sample sizes of 20 and 30 labs. As the target sample size for each code increases, the overall sample sizes increase and so do the number of sampled labs that bill for 80061. In addition, with larger sample sizes, while the three measures of empirical bias for MBS either stayed the same or decreased and the measures of bias for stratified sampling decreased in all cases. With a target sample size of 30 labs, the mean payment rate resulting from the 605 labs sampled by stratified sampling was 0.7% lower than the payment rate from all labs that billed for this code. The relative standard error for MBS stayed at 0 with target sample sizes of 20 and 30 labs and the coverage decreased slightly. Finally, the proportion of testing volume for the sampled labs increased with target sample sizes of 20 and 30 labs.

Independent Labs

| HCPCS Code = 80053 | | | | | | |
|--------------------------------|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 1,636 | | | |
| Number of Labs in Sample | 569 | 322 | 737 | 487 | 851 | 606 |
| Number of Non-Certainty Labs | 119 | 0 | 123 | 0 | 130 | 0 |
| Empirical Bias (Median) | -0.002 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.000 | -0.006 | 0.000 | -0.004 | 0.000 | -0.004 |
| Absolute Empirical Bias (Mean) | 0.007 | 0.006 | 0.004 | 0.004 | 0.003 | 0.004 |
| Relative Standard Error | 0.001 | . | 0.000 | - | 0.000 | - |

| | | | | | | |
|--|-------|-------|-------|-------|-------|-------|
| Coverage | 0.112 | 0.000 | 0.085 | - | 0.076 | - |
| Proportion of Testing Volume in Sample | 0.959 | 0.869 | 0.977 | 0.932 | 0.983 | 0.958 |

| HCPCS Code = 80061 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 1,482 | | | |
| Number of Labs in Sample | 563 | 325 | 724 | 490 | 831 | 605 |
| Number of Non-Certainty Labs | 112 | 0 | 113 | 0 | 117 | 0 |
| Empirical Bias (Median) | -0.007 | -0.049 | -0.005 | -0.046 | -0.003 | -0.033 |
| Empirical Bias (Mean) | 0.000 | -0.013 | 0.000 | -0.010 | 0.000 | -0.007 |
| Absolute Empirical Bias (Mean) | 0.006 | 0.013 | 0.003 | 0.010 | 0.002 | 0.007 |
| Relative Standard Error | 0.000 | . | 0.000 | - | 0.000 | - |
| Coverage | 0.107 | - | 0.091 | - | 0.095 | - |
| Proportion of Testing Volume in Sample | 0.965 | 0.876 | 0.982 | 0.933 | 0.988 | 0.960 |

| HCPCS Code = 82378 | | | | | | |
|------------------------------|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 842 | | | |
| Number of Labs in Sample | 407 | 256 | 510 | 376 | 574 | 451 |
| Number of Non-Certainty Labs | 73 | 0 | 70 | 0 | 70 | 0 |
| Empirical Bias (Median) | -0.001 | 0.000 | -0.001 | 0.000 | 0.000 | 0.000 |

| | | | | | | |
|--|-------|-------|-------|-------|-------|-------|
| Empirical Bias (Mean) | 0.000 | 0.000 | 0.000 | 0.006 | 0.000 | 0.003 |
| Absolute Empirical Bias (Mean) | 0.005 | 0.000 | 0.003 | 0.006 | 0.003 | 0.003 |
| Relative Standard Error | 0.000 | - | 0.000 | - | 0.000 | - |
| Coverage | 0.156 | - | 0.120 | - | 0.085 | - |
| Proportion of Testing Volume in Sample | 0.969 | 0.889 | 0.986 | 0.927 | 0.990 | 0.949 |

HCPCS Code = 83036

| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 1,491 | | | | | |
| Number of Labs in Sample | 560 | 322 | 721 | 486 | 826 | 602 |
| Number of Non-Certainty Labs | 112 | 0 | 112 | 0 | 117 | 0 |
| Empirical Bias (Median) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.000 | -0.008 | 0.000 | -0.002 | 0.000 | -0.005 |
| Absolute Empirical Bias (Mean) | 0.004 | 0.008 | 0.002 | 0.002 | 0.001 | 0.005 |
| Relative Standard Error | 0.000 | - | 0.000 | - | 0.000 | - |
| Coverage | 0.109 | - | 0.152 | - | 0.130 | - |
| Proportion of Testing Volume in Sample | 0.964 | 0.853 | 0.982 | 0.918 | 0.988 | 0.945 |

HCPCS Code = 84445

| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
|------------------------------|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 232 | | | | | |
| Number of Labs in Sample | 197 | 150 | 214 | 191 | 222 | 212 |
| Number of Non-Certainty Labs | 15 | 0 | 8 | 0 | 6 | 0 |
| Empirical Bias (Median) | 0.006 | 0.000 | 0.001 | 0.000 | 0.000 | 0.000 |

| | | | | | | |
|--|-------|--------|-------|--------|-------|--------|
| Empirical Bias (Mean) | 0.000 | -0.005 | 0.000 | -0.002 | 0.000 | -0.001 |
| Absolute Empirical Bias (Mean) | 0.004 | 0.005 | 0.003 | 0.002 | 0.003 | 0.001 |
| Relative Standard Error | 0.001 | - | 0.000 | - | 0.000 | - |
| Coverage | 0.216 | - | 0.086 | - | 0.000 | - |
| Proportion of Testing Volume in Sample | 0.993 | 0.964 | 0.998 | 0.992 | 0.999 | 0.998 |

HCPCS Code = 86003

| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 327 | | | | | |
| Number of Labs in Sample | 249 | 175 | 277 | 232 | 290 | 258 |
| Number of Non-Certainty Labs | 21 | 0 | 13 | 0 | 9 | 0 |
| Empirical Bias (Median) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.000 | 0.007 | -0.001 | -0.082 | 0.000 | -0.068 |
| Absolute Empirical Bias (Mean) | 0.010 | 0.007 | 0.009 | 0.082 | 0.007 | 0.068 |
| Relative Standard Error | 0.001 | - | 0.001 | - | 0.001 | - |
| Coverage | 0.105 | - | 0.028 | - | 0.043 | - |
| Proportion of Testing Volume in Sample | 0.981 | 0.807 | 0.988 | 0.919 | 0.991 | 0.936 |

HCPCS Code = 86148

| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
|------------------------------|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 133 | | | | | |
| Number of Labs in Sample | 121 | 96 | 127 | 116 | 130 | 123 |
| Number of Non-Certainty Labs | 5 | 0 | 3 | 0 | 1 | 0 |
| Empirical Bias (Median) | 0.000 | 0.763 | 0.000 | 0.932 | 0.000 | 0.932 |

| HCPCS Code = 86148 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Empirical Bias (Mean) | 0.000 | 0.168 | 0.000 | 0.303 | 0.000 | 0.301 |
| Absolute Empirical Bias (Mean) | 0.003 | 0.168 | 0.003 | 0.303 | 0.002 | 0.301 |
| Relative Standard Error | 0.000 | - | 0.000 | - | 0.000 | - |
| Coverage | 0.067 | - | 0.002 | - | 0.169 | - |
| Proportion of Testing Volume in Sample | 0.998 | 0.525 | 0.999 | 0.605 | 0.999 | 0.606 |
| HCPCS Code = 87150 | | | | | | |
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 88 | | | | | |
| Number of Labs in Sample | 80 | 61 | 84 | 75 | 87 | 78 |
| Number of Non-Certainty Labs | 5 | 0 | 4 | 0 | 1 | 0 |
| Empirical Bias (Median) | 0.000 | -0.063 | 0.000 | -0.054 | 0.000 | -0.063 |
| Empirical Bias (Mean) | 0.000 | 0.194 | 0.000 | 0.207 | 0.000 | 0.169 |
| Absolute Empirical Bias (Mean) | 0.003 | 0.194 | 0.001 | 0.207 | 0.000 | 0.169 |
| Relative Standard Error | 0.000 | - | 0.000 | - | 0.000 | - |
| Coverage | 0.077 | - | 0.621 | - | 0.000 | - |
| Proportion of Testing Volume in Sample | 0.985 | 0.274 | 0.994 | 0.293 | 1.000 | 0.317 |
| HCPCS Code = 87902 | | | | | | |
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 241 | | | | | |
| Number of Labs in Sample | 202 | 148 | 219 | 193 | 228 | 212 |
| Number of Non-Certainty Labs | 19 | 0 | 8 | 0 | 8 | 0 |
| Empirical Bias (Median) | -0.006 | -0.017 | -0.006 | 0.000 | 0.000 | 0.000 |

| HCPCS Code = 87902 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Empirical Bias (Mean) | 0.000 | -0.004 | 0.000 | 0.000 | 0.000 | 0.000 |
| Absolute Empirical Bias (Mean) | 0.003 | 0.004 | 0.001 | 0.000 | 0.000 | 0.000 |
| Relative Standard Error | 0.001 | - | 0.000 | - | 0.000 | - |
| Coverage | 0.188 | - | 0.072 | - | 0.280 | - |
| Proportion of Testing Volume in Sample | 0.988 | 0.931 | 0.996 | 0.985 | 0.999 | 0.991 |
| HCPCS Code = 88262 | | | | | | |
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 83 | | | | | |
| Number of Labs in Sample | 76 | 68 | 81 | 73 | 82 | 75 |
| Number of Non-Certainty Labs | 3 | 0 | 2 | 0 | 0 | 0 |
| Empirical Bias (Median) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.001 | -0.047 | 0.000 | 0.004 | 0.000 | 0.005 |
| Absolute Empirical Bias (Mean) | 0.011 | 0.047 | 0.002 | 0.004 | 0.001 | 0.005 |
| Relative Standard Error | 0.004 | - | 0.001 | - | . | - |
| Coverage | 0.299 | - | 0.019 | - | 0.000 | - |
| Proportion of Testing Volume in Sample | 0.965 | 0.802 | 0.995 | 0.938 | 1.000 | 0.942 |

Hospital Labs

| HCPCS Code = 80053 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 3,049 | | | |
| Number of Labs in Sample | 1,112 | 549 | 1,534 | 923 | 1,780 | 1,244 |
| Number of Non-Certainty Labs | 372 | 0 | 365 | 0 | 325 | 0 |
| Empirical Bias (Median) | 0.013 | 0.016 | 0.008 | 0.016 | 0.005 | 0.016 |
| Empirical Bias (Mean) | -0.002 | 0.045 | 0.001 | 0.021 | 0.000 | 0.010 |
| Absolute Empirical Bias (Mean) | 0.018 | 0.045 | 0.008 | 0.021 | 0.004 | 0.010 |
| Relative Standard Error | 0.001 | . | 0.001 | . | 0.000 | . |
| Coverage | 0.076 | . | 0.077 | . | 0.066 | . |
| Proportion of Testing Volume in Sample | 0.837 | 0.613 | 0.924 | 0.771 | 0.957 | 0.862 |

| HCPCS Code = 80061 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 2,836 | | | |
| Number of Labs in Sample | 1,093 | 541 | 1,503 | 904 | 1,744 | 1,216 |
| Number of Non-Certainty Labs | 364 | 0 | 357 | 0 | 317 | 0 |
| Empirical Bias (Median) | 0.010 | 0.062 | 0.007 | 0.047 | 0.004 | 0.038 |
| Empirical Bias (Mean) | -0.001 | 0.006 | 0.000 | -0.008 | 0.000 | 0.021 |
| Absolute Empirical Bias (Mean) | 0.022 | 0.006 | 0.010 | 0.008 | 0.005 | 0.021 |
| Relative Standard Error | 0.001 | - | 0.001 | . | 0.000 | . |
| Coverage | 0.069 | - | 0.066 | . | 0.082 | . |
| Proportion of Testing Volume in Sample | 0.847 | 0.628 | 0.932 | 0.785 | 0.962 | 0.872 |

| HCPCS Code = 82378 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 1,405 | | | |
| Number of Labs in Sample | 786 | 422 | 1,021 | 666 | 1,136 | 861 |
| Number of Non-Certainty Labs | 221 | 0 | 181 | 0 | 134 | 0 |
| Empirical Bias (Median) | -0.003 | -0.163 | 0.001 | -0.154 | 0.003 | -0.086 |
| Empirical Bias (Mean) | 0.002 | -0.072 | -0.001 | -0.074 | 0.000 | -0.056 |
| Absolute Empirical Bias (Mean) | 0.030 | 0.072 | 0.016 | 0.074 | 0.010 | 0.056 |
| Relative Standard Error | 0.002 | . | 0.001 | . | 0.001 | . |
| Coverage | 0.086 | . | 0.091 | . | 0.110 | . |
| Proportion of Testing Volume in Sample | 0.891 | 0.695 | 0.954 | 0.812 | 0.976 | 0.886 |

| HCPCS Code = 83036 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 2,824 | | | |
| Number of Labs in Sample | 1,096 | 544 | 1,506 | 910 | 1,744 | 1,223 |
| Number of Non-Certainty Labs | 362 | 0 | 354 | 0 | 311 | 0 |
| Empirical Bias (Median) | -0.001 | 0.026 | 0.000 | 0.006 | 0.001 | 0.006 |
| Empirical Bias (Mean) | -0.001 | 0.017 | 0.000 | 0.014 | 0.000 | 0.004 |
| Absolute Empirical Bias (Mean) | 0.009 | 0.017 | 0.004 | 0.014 | 0.003 | 0.004 |
| Relative Standard Error | 0.001 | . | 0.000 | . | 0.000 | . |
| Coverage | 0.074 | - | 0.071 | 0.000 | 0.088 | . |
| Proportion of Testing Volume in Sample | 0.837 | 0.421 | 0.927 | 0.766 | 0.959 | 0.857 |

| HCPCS Code = 84445 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 579 | | | | | |
| Number of Labs in Sample | 422 | 266 | 502 | 381 | 533 | 451 |
| Number of Non-Certainty Labs | 84 | 0 | 51 | 0 | 38 | 0 |
| Empirical Bias (Median) | 0.004 | 0.004 | 0.005 | 0.021 | 0.004 | 0.021 |
| Empirical Bias (Mean) | 0.000 | 0.009 | 0.000 | 0.014 | 0.000 | 0.010 |
| Absolute Empirical Bias (Mean) | 0.017 | 0.009 | 0.012 | 0.014 | 0.007 | 0.010 |
| Relative Standard Error | 0.002 | . | 0.002 | . | 0.001 | . |
| Coverage | 0.119 | . | 0.126 | . | 0.276 | . |
| Proportion of Testing Volume in Sample | 0.920 | 0.759 | 0.966 | 0.894 | 0.981 | 0.942 |

| HCPCS Code = 86003 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 749 | | | | | |
| Number of Labs in Sample | 520 | 309 | 624 | 464 | 670 | 573 |
| Number of Non-Certainty Labs | 110 | 0 | 73 | 0 | 49 | 0 |
| Empirical Bias (Median) | -0.004 | -0.002 | 0.001 | 0.009 | 0.001 | 0.009 |
| Empirical Bias (Mean) | 0.000 | -0.003 | 0.000 | -0.003 | 0.000 | 0.000 |
| Absolute Empirical Bias (Mean) | 0.011 | 0.003 | 0.004 | 0.003 | 0.003 | 0.000 |
| Relative Standard Error | 0.001 | . | 0.001 | . | 0.000 | . |
| Coverage | 0.085 | . | 0.151 | . | 0.177 | . |
| Proportion of Testing Volume in Sample | 0.922 | 0.779 | 0.974 | 0.876 | 0.988 | 0.952 |

| HCPCS Code = 86148 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 146 | | | |
| Number of Labs in Sample | 116 | 84 | 136 | 112 | 141 | 324 |
| Number of Non-Certainty Labs | 18 | 0 | 10 | 0 | 3 | 0 |
| Empirical Bias (Median) | -0.001 | 0.165 | -0.006 | 0.047 | -0.003 | 0.000 |
| Empirical Bias (Mean) | 0.001 | 0.053 | 0.000 | 0.015 | 0.000 | 0.002 |
| Absolute Empirical Bias (Mean) | 0.015 | 0.053 | 0.006 | 0.015 | 0.004 | 0.002 |
| Relative Standard Error | 0.004 | . | 0.002 | . | 0.002 | . |
| Coverage | 0.292 | . | 0.363 | . | 0.312 | . |
| Proportion of Testing Volume in Sample | 0.941 | 0.829 | 0.981 | 0.935 | 0.990 | 0.960 |

| HCPCS Code = 87150 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 240 | | | |
| Number of Labs in Sample | 160 | 94 | 194 | 142 | 214 | 177 |
| Number of Non-Certainty Labs | 31 | 0 | 31 | 0 | 20 | 0 |
| Empirical Bias (Median) | -0.023 | 0.013 | -0.012 | 0.000 | -0.006 | 0.000 |
| Empirical Bias (Mean) | -0.001 | 0.018 | 0.000 | 0.003 | 0.000 | 0.003 |
| Absolute Empirical Bias (Mean) | 0.021 | 0.018 | 0.011 | 0.003 | 0.006 | 0.003 |
| Relative Standard Error | 0.004 | . | 0.002 | . | 0.001 | . |
| Coverage | 0.229 | . | 0.241 | . | 0.315 | . |
| Proportion of Testing Volume in Sample | 0.778 | 0.368 | 0.886 | 0.702 | 0.952 | 0.836 |

| HCPCS Code = 87902 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 651 | | | | | |
| Number of Labs in Sample | 482 | 292 | 572 | 436 | 605 | 522 |
| Number of Non-Certainty Labs | 96 | 0 | 56 | 0 | 34 | 0 |
| Empirical Bias (Median) | -0.007 | 0.000 | -0.007 | 0.032 | -0.009 | 0.015 |
| Empirical Bias (Mean) | 0.000 | 0.018 | 0.001 | 0.020 | 0.000 | 0.012 |
| Absolute Empirical Bias (Mean) | 0.017 | 0.018 | 0.010 | 0.020 | 0.007 | 0.012 |
| Relative Standard Error | 0.002 | . | 0.001 | . | 0.001 | . |
| Coverage | 0.124 | . | 0.153 | . | 0.194 | . |
| Proportion of Testing Volume in Sample | 0.892 | 0.667 | 0.960 | 0.648 | 0.977 | 0.918 |

| HCPCS Code = 88262 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 86 | | | | | |
| Number of Labs in Sample | 70 | 56 | 78 | 67 | 82 | 72 |
| Number of Non-Certainty Labs | 9 | 0 | 4 | 0 | 6 | 0 |
| Empirical Bias (Median) | 0.034 | -0.003 | 0.011 | 0.000 | 0.003 | 0.000 |
| Empirical Bias (Mean) | 0.000 | -0.028 | 0.001 | 0.016 | 0.000 | 0.010 |
| Absolute Empirical Bias (Mean) | 0.034 | 0.028 | 0.013 | 0.016 | 0.007 | 0.010 |
| Relative Standard Error | 0.009 | . | 0.004 | . | 0.002 | . |
| Coverage | 0.338 | . | 0.187 | . | 0.296 | . |
| Proportion of Testing Volume in Sample | 0.930 | 0.853 | 0.972 | 0.913 | 0.987 | 0.913 |

Physician Office Labs

| HCPCS Code = 80053 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 2,508 | | | | | |
| Number of Labs in Sample | 957 | 469 | 1,303 | 743 | 1,523 | 951 |
| Number of Non-Certainty Labs | 281 | 0 | 291 | 0 | 267 | 0 |
| Empirical Bias (Median) | 0.010 | 0.145 | -0.010 | 0.080 | 0.000 | 0.078 |
| Empirical Bias (Mean) | 0.000 | 0.952 | 0.000 | 0.471 | 0.002 | 0.300 |
| Absolute Empirical Bias (Mean) | 0.067 | 0.952 | 0.042 | 0.471 | 0.032 | 0.300 |
| Relative Standard Error | 0.007 | . | 0.005 | . | 0.003 | . |
| Coverage | 0.071 | . | 0.063 | . | 0.063 | . |
| Proportion of Testing Volume in Sample | 0.626 | 0.368 | 0.761 | 0.519 | 0.821 | 0.617 |

| HCPCS Code = 80061 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 2,498 | | | | | |
| Number of Labs in Sample | 947 | 469 | 1,291 | 745 | 1,508 | 953 |
| Number of Non-Certainty Labs | 279 | 0 | 290 | 0 | 270 | 0 |
| Empirical Bias (Median) | -0.003 | -0.101 | -0.008 | -0.075 | -0.010 | -0.101 |
| Empirical Bias (Mean) | -0.004 | -0.071 | -0.001 | -0.065 | -0.001 | -0.088 |
| Absolute Empirical Bias (Mean) | 0.103 | 0.071 | 0.062 | 0.065 | 0.048 | 0.088 |
| Relative Standard Error | 0.007 | . | 0.004 | . | 0.003 | . |
| Coverage | 0.088 | . | 0.072 | . | 0.071 | . |
| Proportion of Testing Volume in Sample | 0.577 | 0.147 | 0.713 | 0.490 | 0.778 | 0.590 |

| HCPCS Code = 82378 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 338 | | | | | |
| Number of Labs in Sample | 206 | 122 | 254 | 165 | 278 | 196 |
| Number of Non-Certainty Labs | 42 | 0 | 31 | 0 | 27 | 0 |
| Empirical Bias (Median) | -0.015 | -0.199 | -0.013 | -0.227 | -0.009 | -0.130 |
| Empirical Bias (Mean) | 0.001 | -0.126 | -0.001 | -0.067 | -0.002 | -0.030 |
| Absolute Empirical Bias (Mean) | 0.057 | 0.126 | 0.036 | 0.067 | 0.024 | 0.030 |
| Relative Standard Error | 0.007 | . | 0.005 | . | 0.003 | . |
| Coverage | 0.143 | . | 0.180 | . | 0.231 | . |
| Proportion of Testing Volume in Sample | 0.764 | 0.513 | 0.884 | 0.602 | 0.927 | 0.690 |

| HCPCS Code = 83036 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | 2,671 | | | | | |
| Number of Labs in Sample | 934 | 460 | 1,289 | 738 | 1,520 | 949 |
| Number of Non-Certainty Labs | 285 | 0 | 303 | 0 | 292 | 0 |
| Empirical Bias (Median) | 0.006 | -0.165 | -0.002 | 0.036 | -0.005 | -0.045 |
| Empirical Bias (Mean) | -0.002 | -0.131 | -0.002 | 0.112 | 0.003 | 0.067 |
| Absolute Empirical Bias (Mean) | 0.141 | 0.131 | 0.098 | 0.112 | 0.072 | 0.067 |
| Relative Standard Error | 0.008 | . | 0.006 | . | 0.004 | . |
| Coverage | 0.078 | . | 0.068 | . | 0.065 | . |
| Proportion of Testing Volume in Sample | 0.521 | 0.296 | 0.660 | 0.434 | 0.732 | 0.541 |

| HCPCS Code = 84445 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 54 | | | |
| Number of Labs in Sample | 44 | 33 | 47 | 42 | 51 | 47 |
| Number of Non-Certainty Labs | 5 | 0 | 3 | 0 | 3 | 0 |
| Empirical Bias (Median) | 0.009 | -0.327 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.000 | 0.130 | 0.000 | 0.026 | 0.000 | 0.007 |
| Absolute Empirical Bias (Mean) | 0.011 | 0.130 | 0.006 | 0.026 | 0.003 | 0.007 |
| Relative Standard Error | 0.005 | . | 0.003 | . | 0.002 | . |
| Coverage | 0.374 | . | 0.213 | . | 0.307 | . |
| Proportion of Testing Volume in Sample | 0.962 | 0.720 | 0.988 | 0.919 | 0.994 | 0.987 |

| HCPCS Code = 86003 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 155 | | | |
| Number of Labs in Sample | 107 | 69 | 124 | 85 | 138 | 99 |
| Number of Non-Certainty Labs | 22 | 0 | 17 | 0 | 13 | 0 |
| Empirical Bias (Median) | 0.131 | 6.161 | 0.010 | 0.296 | 0.008 | -0.312 |
| Empirical Bias (Mean) | -0.018 | 0.563 | -0.003 | 0.334 | 0.001 | -0.214 |
| Absolute Empirical Bias (Mean) | 0.209 | 0.563 | 0.111 | 0.334 | 0.046 | 0.214 |
| Relative Standard Error | 0.035 | . | 0.018 | . | 0.010 | . |
| Coverage | 0.260 | . | 0.298 | . | 0.328 | . |
| Proportion of Testing Volume in Sample | 0.722 | 0.192 | 0.858 | 0.230 | 0.947 | 0.569 |

| HCPCS Code = 86148 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 19 | | | |
| Number of Labs in Sample | 18 | 16 | 19 | 19 | 19 | 19 |
| Number of Non-Certainty Labs | 0 | 0 | 0 | 0 | 0 | 0 |
| Empirical Bias (Median) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.000 | 0.094 | 0.000 | 0.000 | 0.000 | 0.000 |
| Absolute Empirical Bias (Mean) | 0.000 | 0.094 | 0.000 | 0.000 | 0.000 | 0.000 |
| Relative Standard Error | . | . | . | . | . | . |
| Coverage | 0.000 | . | 0.000 | . | 0.000 | . |
| Proportion of Testing Volume in Sample | 1.000 | 0.751 | 1.000 | 1.000 | 1.000 | 1.000 |

| HCPCS Code = 87150 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 12 | | | |
| Number of Labs in Sample | 11 | 10 | 12 | 12 | 12 | 12 |
| Number of Non-Certainty Labs | 2 | 2 | 0 | 0 | 0 | 0 |
| Empirical Bias (Median) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Absolute Empirical Bias (Mean) | 0.001 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Relative Standard Error | 0.000 | 0.047 | . | . | . | . |
| Coverage | 0.165 | 1.000 | 0.000 | . | 0.000 | . |
| Proportion of Testing Volume in Sample | 0.996 | 0.993 | 1.000 | 1.000 | 1.000 | 1.000 |

| HCPCS Code = 87902 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 33 | | | |
| Number of Labs in Sample | 30 | 28 | 32 | 31 | 33 | 32 |
| Number of Non-Certainty Labs | 1 | 0 | 1 | 0 | 1 | 0 |
| Empirical Bias (Median) | -0.002 | -0.005 | -0.001 | -0.005 | -0.001 | -0.003 |
| Empirical Bias (Mean) | 0.000 | -0.008 | 0.000 | -0.011 | 0.000 | -0.006 |
| Absolute Empirical Bias (Mean) | 0.015 | 0.008 | 0.008 | 0.011 | 0.003 | 0.006 |
| Relative Standard Error | 0.006 | . | 0.000 | . | . | . |
| Coverage | 0.202 | . | 0.000 | . | 0.000 | . |
| Proportion of Testing Volume in Sample | 0.987 | 0.971 | 0.996 | 0.990 | 0.999 | 0.995 |

| HCPCS Code = 88262 | | | | | | |
|--|--------------------------|---------------------|--------------------------|---------------------|--------------------------|---------------------|
| | Target Sample Size 10 | | Target Sample Size 20 | | Target Sample Size 30 | |
| | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling | Maximal Brewer Selection | Stratified Sampling |
| Number of Labs with Data | | | 10 | | | |
| Number of Labs in Sample | 10 | 10 | 10 | 10 | 10 | 10 |
| Number of Non-Certainty Labs | 0 | 0 | 0 | 0 | 0 | 0 |
| Empirical Bias (Median) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Empirical Bias (Mean) | 0.000 | 0.000 | 0.000 | 0 | 0.000 | 0 |
| Absolute Empirical Bias (Mean) | 0.000 | 0.000 | 0.000 | 0 | 0.000 | 0 |
| Relative Standard Error | . | . | . | . | . | . |
| Coverage | 0.000 | . | 0.000 | . | 0.000 | . |
| Proportion of Testing Volume in Sample | 1.000 | 1 | 1.000 | 1 | 1.000 | 1 |

Source: RTI International analysis of 2018 Medicare claims and CMS private payer rate data.