

Frequency and Costs of Out-of-Network Bills for Outpatient Laboratory Services Among Privately Insured Patients

Aditi P. Sen, PhD; Mark K. Meiselbach, BS; Yang Wang, BS; Matthew D. Eisenberg, PhD; Gerard F. Anderson, PhD

[+ Supplemental content](#)

IMPORTANCE Patients may be unaware of which laboratory is processing their clinical tests, limiting their ability to choose an in-network laboratory. Out-of-network laboratory services could increase patients' out-of-pocket costs and their reluctance to obtain necessary tests.

OBJECTIVE To evaluate the frequency and cost of out-of-network bills for outpatient laboratory services compared with other services.

DESIGN, SETTING, AND PARTICIPANTS This retrospective cohort study of claims data from the Truven MarketScan Commercial Claims database evaluated claims from 3 946 210 individuals (30.5% of the total) in the MarketScan database who were continually enrolled in health maintenance organization plans, preferred provider organization plans, exclusive provider organization plans, or consumer-driven health plans/high-deductible health plans with at least 1 outpatient clinical laboratory service in 2018. Outpatient laboratory services occurred in independent laboratories, physician offices, and outpatient centers. Laboratory bills from January 1, 2010, to December 31, 2018, were studied.

EXPOSURES Receipt and cost of outpatient laboratory service.

MAIN OUTCOMES AND MEASURES The primary outcome was the proportion of outpatient laboratory services billed as out of network. The secondary outcome was the total potential out-of-pocket cost associated with the out-of-network bill, the sum of observed cost sharing, and the potential balance bill.

RESULTS Of the 12 958 130 in the total sample, 30.5% (3 946 210) had a laboratory test, of whom 5.9% received an out-of-network laboratory test. In comparison, 7.1% of the total sample had an emergency department visit, of whom 4.9% had a service billed as out of network, and 1.6% had an inpatient anesthesiology service, of whom 3.4% had an out-of-network service. Observed out-of-pocket spending was \$24.59 higher for an out-of-network laboratory service than an in-network laboratory service. In addition, patients with an out-of-network laboratory service may receive an additional balance bill from the laboratory service; the estimated mean balance bill was \$80.63. For the most common laboratory services, the total potential out-of-pocket cost associated with an out-of-network bill ranged from \$15.68 for venipuncture to \$88.09 for lipid panel but was as high as \$303.18 for a drug screening test.

CONCLUSIONS AND RELEVANCE In this cohort study, out-of-network laboratory services were 5 times more common than out-of-network emergency department visits and 34 times more common than out-of-network anesthesiology services. It is important for patients that consumer protections against out-of-network bills apply to laboratory services.

JAMA Intern Med. 2021;181(6):834-841. doi:10.1001/jamainternmed.2021.1422
Published online April 26, 2021.

Author Affiliations: Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland.

Corresponding Author: Aditi P. Sen, PhD, Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, 624 N Broadway, Baltimore, MD 21205 (asen@jhu.edu).

Clinical laboratory services are the highest-volume medical activity in the US, with more than 14 billion tests ordered annually and 70% of medical decisions reliant on laboratory results.^{1,2} Although routine laboratory tests are often performed in physicians' offices, samples may be sent to independent laboratories for analysis without the patient being able to determine whether that laboratory is in their insurance network. If the laboratory is out of network, the insurer may cover only a portion of the bill, leaving the patient responsible for the balance between the charge and the amount covered by the patient's insurer. We examined whether out-of-network services in the outpatient clinical laboratory services sector are associated with significant out-of-pocket costs for patients, which could impact willingness to receive a laboratory test in the future. Although the US Congress recently passed legislation protecting patients from out-of-network bills when they unknowingly receive out-of-network care, laboratory services have not been a major component of the policy debate.

Previous studies³⁻⁶ have focused on out-of-network billing in the context of emergency department visits, air ambulances, and anesthesiology services. To date, however, there is limited research examining out-of-network bills for laboratory services, despite the volume of use and substantial potential for out-of-network bills. Previous work⁷ has found that out-of-network spending on clinical laboratory tests is increasing, in contrast to decreasing out-of-network spending in other service areas (eg, emergency department). However, little evidence is available on the effects on patients. In this study, we used national commercial claims data to evaluate the frequency and amount of out-of-pocket costs associated with out-of-network outpatient laboratory services.

Methods

Data Source

The primary data for this study were from the Truven Health MarketScan database, which includes claims for health care services from 350 different insurers who provide coverage for approximately 25% of individuals with commercial insurance and their families in the US.⁸ These data have been used in numerous studies⁹⁻¹¹ to assess health care service use and spending. Of importance, these data include a network status variable for all claims that indicates whether the service was billed as an out-of-network service. The data also include actual prices (allowed amounts) paid for in- and out-of-network services and patient cost-sharing information. We studied laboratory bills from January 1, 2010, to December 31, 2018. The main results discussed in this article focus on the most recent data (2018). The Johns Hopkins School of Medicine Institutional Review Board deemed that this study did not require approval because it did not constitute human subjects research and used deidentified data. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Patient cost sharing observed in the data does not capture the amount a patient might be billed if an out-of-network independent laboratory charges them directly for the

Key Points

Question How does the likelihood of a patient receiving an out-of-network bill for outpatient laboratory services compare with other services, and how costly are these bills for patients?

Findings In this cohort study, 6% of 3 946 210 commercially insured individuals with an outpatient laboratory received a laboratory service billed out of network in 2018, affecting considerably more patients than out-of-network bills for other services. Observed out-of-pocket spending was \$25 higher for an out-of-network laboratory service than an in-network laboratory service with the potential for an additional \$81 balance bill on average.

Meaning These findings indicate that millions of Americans receive laboratory services and are at risk for substantial costs attributable to out-of-network bills.

difference between the full charge and the amount covered by the patient's insurance. We estimated this potential balance bill using charge data as in previous work.^{12,13} Because MarketScan data do not include information on service charges, we obtained submitted charges for clinical laboratory tests from publicly available Medicare Provider Utilization and Payment Data. Use of these data is suitable because charged amounts are constant across insurers (although amount billed and paid varies). Because MarketScan data do not allow us to identify specific health care professionals, we took a mean of health care professional-level charges in the Medicare data at the level of the state, year, and *Current Procedural Terminology* (CPT) code (weighted by number of services provided by health care professionals). We then merged charges by state, year, and CPT with claim-level data from MarketScan. The Medicare data include charge information for 88% percent of laboratory CPT codes in our data (incomplete coverage is because Medicare does not cover all laboratory tests).

Cohort Selection

MarketScan data are sourced from large employers and directly from insurers; because of changes in the insurer-sourced sample during our study period, we used only data from self-insured plans (71.3% of the full MarketScan data in 2018). Our sample consisted of individuals who were continuously enrolled in 1 of the following plan types because we expect these plan designs to have different incentives (eg, cost sharing) for in- vs out-of-network services: health maintenance organization (HMO) plans, preferred provider organization (PPO) plans, consumer-driven health plans and high-deductible health plans (CDHPs/HDHPs), and exclusive provider organization (EPO) plans. In 2018, this sample consisted of 12 958 130 individuals, of whom 3 946 210 (30.5%) underwent at least 1 laboratory test in an outpatient setting (independent laboratory, physician office, hospital outpatient department, or other setting). Inpatient laboratory services were excluded from the analysis.

Laboratory services were identified in the outpatient database based on a laboratory provider type indicator (facility, physician, other health care professional, or other agency providing the service). Each laboratory service was associated with

a CPT code. We excluded services associated with Healthcare Common Procedure Coding System codes (eg, physician-administered drugs) (1.2%) and with negative total paid amounts (0.1%). Laboratory setting was identified based on place of service code. Individuals in our sample had a total of 36 839 043 laboratory services in 2018, of which 33 249 646 occurred in an independent laboratory, 2 496 421 in a physician office, 572 755 in a hospital outpatient department, and 520 221 in other settings.

We compared the percentage of patients receiving a laboratory service billed as out of network with the percentage of patients receiving emergency department and inpatient anesthesiology services billed as out of network. Anesthesiology services were identified in the inpatient database based on professional service claims. Emergency department visits and associated professional services were identified based on an emergency department place setting.

Outcomes

The primary outcome was the percentage of outpatient laboratory services (ie, claims) billed as out of network. A related outcome was the percentage of individuals with at least 1 laboratory service billed as out of network. We examined these outcomes separately for laboratory services that occurred in offices and independent laboratories, the 2 main settings for laboratory services.

The second outcome of interest was the per-laboratory and annual total potential out-of-pocket cost associated with out-of-network laboratory services. Total potential out-of-pocket cost per laboratory service was calculated as the sum of (1) out-of-pocket spending observed for the laboratory claim (eg, patient copayment) and (2) the estimated balance bill associated with that service. The estimated balance bill was calculated as the difference between the mean charge for the laboratory service at the state-year-CPT level reported in publicly available Medicare data and the total allowed amount for that claim observed in the MarketScan data. In rare cases (2.3%), allowed amounts in MarketScan were greater than the mean charge; in these cases, the estimated balance bill was set at 0. We captured 4 payment measures associated with each laboratory service: (1) mean state-year-CPT charge, (2) claim-level total allowed amount, (3) estimated balance bill (charge minus allowed amount), and (4) claim-level out-of-pocket spending. Total potential out-of-pocket cost is the sum of the estimated balance bill and claim-level out-of-pocket spending; it is an upper bound of potential spending because this sum assumes the patient would be responsible for the full balance bill.

Statistical Analysis

We calculated the percentage of laboratory services billed as out of network and the percentage of patients with a laboratory service billed as out of network separately by setting. We characterized in- vs out-of-network laboratory services in terms of plan type associated with the claim, patient characteristics, and geographic region. We described the variation in percentage of laboratory services billed as out of network across states and compared it with the percentage of out-of-network bills in emergency department and inpatient anesthesiology services.

To examine the financial costs to patients associated with out-of-network laboratories, we calculated the 4 payment measures described above and the total potential out-of-pocket cost associated with each laboratory service. Because the types of laboratory services that are billed as out of network might differ from those that are not billed as out of network, we reweighted the distribution of in-network laboratory services to match the frequency of out-of-network services to compare prices. To reweight, we calculated the proportion of total out-of-network laboratory services attributable to each CPT code as well as in-network mean charges, allowed amounts, and out-of-pocket expenditures for each CPT code. We then computed a weighted mean of the CPT-level cost measures using the out-of-network frequency weights.

We assessed the frequency and magnitude of out-of-network laboratory bills for the most common and highest-expenditure laboratory services and estimated total annual potential out-of-pocket costs associated with out-of-network laboratory services relative to in-network laboratory services. Finally, we used regression analysis to estimate patient and insurance factors related to out-of-network laboratory bills and associated costs. Statistical analyses were performed in Stata software, version 16 (StataCorp LLC), SAS software, version 9.4 (SAS Institute Inc), and R software, version 3.6.1 (R Foundation for Statistical Computing).

Results

In our sample of 12 958 130 individuals continuously enrolled in self-insured HMO, PPO, CDHP/HDHP, and EPO plans, 30.5% (3 946 210) individuals had at least 1 outpatient laboratory service in 2018, of whom 5.9% had an out-of-network laboratory service. In comparison, 7.1% had an emergency department visit, of whom 4.9% had a service billed as out of network, and 1.6% had an inpatient anesthesiology service, of whom 3.4% had an out-of-network service.

The prevalence of out-of-network laboratory use decreased during the years 2016-2018 but remained higher in 2018 (5.9% of individuals with an outpatient laboratory service had an out-of-network laboratory bill) than in 2010 (3.8%), whereas emergency department and inpatient anesthesiology out-of-network service prevalence generally decreased or remained steady during the 2010-2018 period. In all years, out-of-network laboratory bills affected more patients than the combination of out-of-network bills for emergency department visits and inpatient anesthesiology visits, resulting in higher mean total out-of-pocket expenditures on out-of-network laboratory services than on out-of-network emergency department or inpatient anesthesiology services (eTable 1 in the Supplement).

In 2018, 90% of outpatient laboratory services were provided in an independent laboratory and 6.8% in a physician office (Table 1¹⁴). The percentage of services that were billed out of network was 5.2% among independent laboratory services and 3.8% among physician office laboratory services. The percentage of patients who received a laboratory service in an

Table 1. Characteristics of In- vs Out-of-Network Laboratory Services, 2018 (N = 3 946 210)^a

Characteristic	Office-based laboratory services		Independent laboratory services	
	In network	Out of network	In network	Out of network
Services, No.	2 401 852	94 569	31 509 410	1 740 236
People with at least 1 service, No. (%)	346 401 (8.8)	13 051 (0.3)	3 495 577 (88.6)	207 158 (5.2)
Annual services per enrollee among enrollees with at least 1 service, median (IQR)	6 (2-12)	13 (5-29)	11 (3-11)	10 (4-21)
Services by insurance plan type, No. (column %) [row %]				
EPO	143 498 (6.0) [32.9]	260 (0.3) [0.1]	282 738 (0.9) [64.7]	10 297 (0.6) [2.4]
HMO	118 112 (4.9) [2.8]	2719 (2.9) [0.1]	3 751 584 (11.9) [89.9]	298 770 (17.2) [7.2]
PPO	1 749 607 (72.8) [8.6]	75 579 (79.9) [0.4]	17 763 605 (56.4) [86.9]	855 478 (49.2) [4.2]
CDHP/HDHP	390 635 (16.3) [3.7]	16 011 (16.9) [0.1]	9 711 483 (30.8) [90.8]	575 691 (33.1) [5.4]
Services by region, No. (column %) [row %]				
Northeast	210 393 (8.8) [2.2]	7438 (7.9) [0.1]	8 957 651 (28.4) [93.0]	456 785 (26.2) [4.7]
North Central	541 790 (22.6) [11.1]	7959 (8.4) [0.2]	3 979 390 (12.6) [81.2]	371 083 (21.3) [7.6]
South	1 205 533 (50.2) [7.7]	57 212 (60.5) [0.4]	13 713 279 (43.5) [87.7]	667 097 (38.3) [4.3]
West	441 329 (18.4) [8.1]	21 876 (23.1) [0.4]	4 750 715 (15.1) [87.0]	243 964 (14.0) [4.5]
Unknown	2807 (0.1) [2.5]	84 (0.1) [0.1] ^b	108 375 (0.3) [96.3]	1307 (0.1) [1.2]
Age, mean (SD), y	42.30 (15.01)	44.37 (14.01)	42.31 (15.13)	41.80 (14.84)
Female, No. (%)	1 559 842 (64.9)	57 048 (60.3)	20 366 166 (64.6)	1 109 009 (63.7)
No. of Elixhauser conditions, mean (SD)	1.73 (1.95)	2.20 (2.36)	1.86 (2.01)	2.16 (2.23)

Abbreviations: CDHP/HDHP, consumer-driven health plan/high-deductible health plan; EPO, exclusive provider organization; HMO, health maintenance organization; IQR, interquartile range; PPO, preferred provider organization.

^a Sample includes individuals in the MarketScan employer sample with at least 1 outpatient laboratory service in 2018 and continuous annual enrollment in 1 of the following plan types: HMO, PPO, CDHP/HDHP, or EPO. Outpatient laboratory services are identified in outpatient claims based on a laboratory provider type (facility, physician, other professional, or other agency providing the service) not associated with a Healthcare Common Procedure Coding

System code. Out-of-network services were identified based on the MarketScan billed as out-of-network indicator. 2-tailed *t* tests were used to compute *P* values comparing in- vs out-of-network services for continuous variables, and χ^2 tests were used to compute *P* values comparing in- vs out-of-network services for categorical variables. All comparisons were statistically significantly different (*P* < .001 except where noted). Chronic conditions were defined according to Elixhauser comorbidity measures.¹⁴

^b *P* = .01.

independent laboratory that was billed as out of network was 5.2% (0.3% physician offices).

Patients with an out-of-network laboratory service had almost double the number of laboratory services than patients with exclusively in-network laboratory services (median of 27 vs 15 laboratory services). Mean patient age and percentage of female patients were similar across settings and in- vs out-of-network laboratories; however, the patients who received out-of-network laboratory services had slightly more chronic conditions than the patients using in-network laboratory services. The HMO enrollees had the greatest percentage of laboratory services billed out of network (7.2%), followed by those in HDHPs/CDHPs (5.5%) (Table 1). The percentage of outpatient laboratory services billed out of network varied across states, from 1% in Alabama to 26% in Michigan (Figure 1). The rate of outpatient laboratory services billed out of network did not appear to be concentrated in a particular geographic area but was instead a function of total laboratory volume (eFigures 1-4 in the Supplement).

Payments for out-of-network laboratory services were higher than payments for in-network services in terms of reported charge, observed allowed amount, and observed out-of-pocket payment (Figure 2 and eTable 2 in the Supplement). The mean (SD) estimated balance bill for an out-of-

network lab service was \$80.63 (\$264.27). The median estimated balance bill for an out-of-network service was \$48.22 (interquartile range [IQR], \$12.63-\$75.90) (eTable 3 in the Supplement). The difference in mean (SD) estimated charge between out-of-network (\$144.60 [\$340.81]) and in-network (\$79.29 [\$122.99]) laboratory services suggests that the types of laboratories that are out of network may be systematically different from those that are in network. Once the distribution of in-network laboratory services was reweighted to match the frequency of out-of-network services, estimated charges for in-network and out-of-network laboratory services were roughly comparable (\$129.66 vs \$144.60), but a sizable difference remained in observed total payment for in- vs out-of-network services (\$33.14 vs \$63.97) and in observed out-of-pocket payment for in- vs out-of-network services (\$8.15 vs \$32.74). The mean (SD) total potential out-of-pocket cost per laboratory service was \$113.37 (\$216.40) compared with \$8.15 (\$19.20) for in-network services; this difference is an upper bound because it assumes that the patient is billed and pays the full balance bill.

Among the 5 most common laboratory services, a mean (SD) of 3.5% (0.2%) of patients who received these services had the service billed as out of network (Table 2). When the mean observed out-of-pocket cost and the mean estimated balance

Figure 1. Geographic Variation in Rates of Out-of-Network Outpatient Laboratory Bills by State, 2018

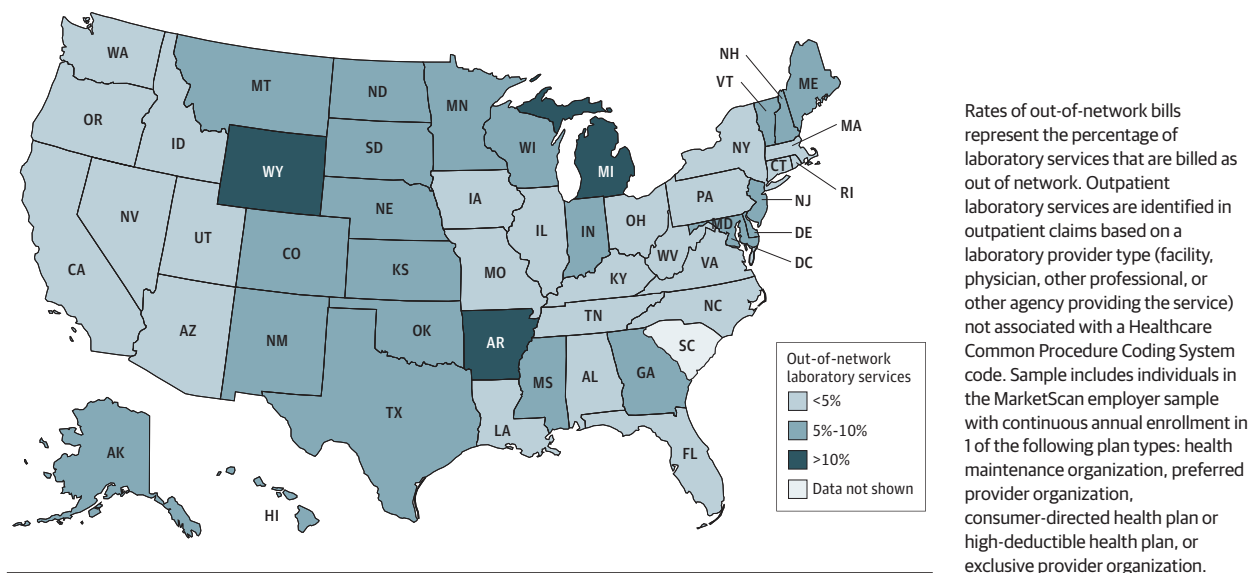
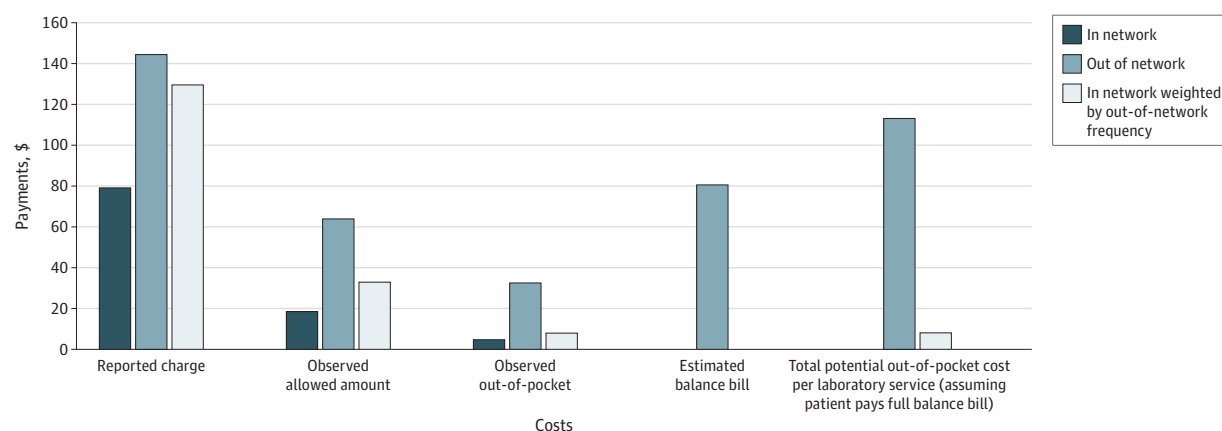


Figure 2. Payments for In- vs Out-of-Network Laboratory Services, 2018



Sample includes individuals in the MarketScan employer sample with continuous annual enrollment in 1 of the following plan types: health maintenance organization, preferred provider organization, consumer-directed health plan or high-deductible health plan, or exclusive provider organization. Sample of patients with *Current Procedural Terminology (CPT)* codes includes those with charge information in the Medicare Provider Utilization and Payment Data. Outpatient laboratory services are identified in outpatient claims based

on a laboratory provider type (facility, physician, other professional, or other agency providing the service) not associated with a Healthcare Common Procedure Coding System code. Out-of-network services were identified based on the MarketScan billed as out-of-network indicator. Estimated balance bill was calculated based on the difference between the publicly reported Medicare charge at the state *CPT* level and the total allowed amount for that service observed in MarketScan data as described in the text.

bill were summed, the total potential out-of-pocket cost ranged from \$15.68 for a venipuncture to \$88.09 for a lipid panel (compared with out-of-pocket spending on in-network services of \$0.61 for a venipuncture and \$3.14 for a lipid panel). Among the highest expenditure laboratory services (based on both the volume and paid amount), the percentage of patients receiving out-of-network laboratory services ranged from 3% for a general health panel to 20% for a drug screening test. For these laboratory services, total potential out-of-pocket cost associated with out-of-network services ranged from \$87.16 for a lipid panel to \$303.18 for a drug screening test (compared with \$3.14

for a lipid panel and \$86.56 for a drug screening test in network).

Finally, we examined total annual laboratory services use and spending among individuals with and without an out-of-network laboratory service in 2018 (Table 3). Patients with an out-of-network laboratory service had a median of 9 total services (IQR, 4-20), with 4 out-of-network services. For these patients, the total median potential out-of-pocket cost (observed out-of-pocket plus estimated potential balance bill) was \$339.13 (IQR, \$148.03-\$930.38); this total assumes that the patient paid the full balance bill and captures both higher

Table 2. Prevalence and Magnitude of Out-of-Network Laboratory Bills for Most Common and Highest Expenditure Laboratory Tests, 2018 (N = 3 946 210)^a

Test (CPT code)	Individuals receiving laboratory services, No.	Individuals receiving out-of-network laboratory services, No. (%)	Mean (SD), \$		Observed out-of-pocket payment in MarketScan data		Estimated balance bill
			Observed allowed amount in MarketScan data		In network	Out of network	
Lipid panel (80061)	1 837 471	59 935 (3.3)	11.31 (11.52)	29.77 (41.61)	3.14 (6.41)	19.32 (31.59)	68.77 (21.61)
Venipuncture (36415)	1 227 865	39 765 (3.2)	2.89 (15.76)	3.57 (8.56)	0.61 (1.96)	2.23 (5.27)	13.45 (4.20)
Comprehensive metabolic panel (80053)	1 189 881	41 958 (3.5)	9.77 (15.62)	24.58 (63.77)	3.69 (6.96)	16.02 (32.78)	41.41 (10.11)
Complete blood cell counts (85025)	971 823	35 637 (3.7)	7.50 (17.89)	15.01 (25.91)	2.44 (4.55)	9.89 (18.47)	26.41 (7.12)
Glycated hemoglobin (83036)	1 001 116	36 261 (3.6)	9.32 (16.81)	22.77 (28.75)	2.43 (4.93)	15.09 (22.46)	43.16 (13.22)
Drug screening test(s), presumptive, any number of drug classes (80307)	89 709	18 033 (20.1)	80.65 (228.19)	342.74 (610.81)	22.50 (62.16)	86.56 (221.84)	216.62 (120.05)
Surgical pathology, gross and microscopic examination (88305)	258 794	12 688 (4.9)	104.14 (129.56)	139.05 (277.17)	29.54 (56.16)	81.71 (163.09)	87.27 (54.85)
General health panel (80050)	1 058 043	32 207 (3.0)	28.30 (21.80)	67.03 (85.55)	8.81 (15.24)	45.64 (66.62)	NA
Vitamin D testing (82306)	810 878	35 096 (4.3)	26.71 (25.01)	73.29 (94.40)	9.59 (16.07)	50.04 (74.25)	129.99 (39.33)

Abbreviation: NA, not available (no available Medicare data on charges).

^a Sample includes individuals in the MarketScan employer sample with at least 1 outpatient laboratory service in 2018 and continuous annual enrollment in 1 of the following plan types: health maintenance organization, preferred provider organization, consumer-driven health plan/high deductible health plan; or exclusive provider organization. Unique laboratory tests were identified based on *Current Procedural Terminology* (CPT) codes. The CPT codes 80061, 36415, 80053, 85025, and 83036 are the most common codes in terms of individuals receiving the laboratory service. The CPT codes 80307, 88305, 80050, 82306, and 80061 are the highest total expenditure laboratory

services (in terms of volume × paid amount). Only laboratory tests with at least 100 unique patients in 2018 were included. Outpatient laboratory services are identified in outpatient claims based on a laboratory provider type (facility, physician, other professional, or other agency providing the service) not associated with a Healthcare Common Procedure Coding System code. Out-of-network services were identified based on the MarketScan billed as out-of-network indicator. Estimated balance bill was calculated based on the difference between the publicly reported Medicare charge at the state and CPT level and the total allowed amount for that service observed in MarketScan data as described in the text.

Table 3. Annual Laboratory Service Use and Spending Among Patients With and Without at Least 1 Laboratory Service Billed as Out of Network, 2018 (N = 3 946 210)^a

Service and spending	Mean	25th Percentile	50th Percentile	75th Percentile
Individuals with at least 1 laboratory service billed out of network (n = 230 859)				
Annual laboratory services, No.	15.85	4	9	20
Annual out-of-network laboratory services, No.	7.86	2	4	8
Annual observed allowed amount for laboratory services, \$	681.76	43.39	194.39	577.35
Annual observed out-of-pocket spending for laboratory services, \$	296.23	4.93	81.88	290.29
Annual estimated balance bills for laboratory services, \$	634.15	55.67	172.35	469.05
Annual total potential out-of-pocket cost (observed out-of-pocket spending for laboratory services plus estimated balance bills for laboratory services), \$	930.38	148.03	339.13	838.33
Individuals with at least 1 laboratory service but none billed out of network (n = 3 715 351)				
Annual laboratory services, No.	8.47	2	5	11
Annual out-of-network laboratory services, No.	0	0	0	0
Annual observed allowed amount for laboratory services, \$	155.24	30.17	69.92	156.10
Annual total out-of-pocket cost (observed out-of-pocket spending for laboratory services)	40.81	0	10.51	40.77

^a Sample includes individuals in the MarketScan employer sample with continuous annual enrollment in 1 of the following plan types: health maintenance organization, preferred provider organization, consumer-driven health plan/high deductible health plan; or exclusive provider organization. Sample of *Current Procedural Terminology* (CPT) codes includes those with charge information in the Medicare Provider Utilization and Payment Data. Outpatient laboratory services are identified in outpatient claims based on a

laboratory provider type (facility, physician, other professional, or other agency providing the service) not associated with a Healthcare Common Procedure Coding System code. Out-of-network services identified based on the MarketScan billed as out-of-network indicator. Estimated balance bill was calculated based on the difference between the publicly reported Medicare charge at the state and CPT level and the total allowed amount for that service observed in MarketScan data as described in the text.

volume of laboratory services and the higher cost per laboratory service. In comparison, patients with at least 1 outpatient laboratory service but none out of network had fewer total laboratory services and lower spending overall; the median total out-of-pocket cost in this subpopulation was \$10.51 (IQR, \$0-\$40.81). Regression analysis found that an out-of-network laboratory service was associated with approximately \$37 higher out-of-pocket expenditures per laboratory service received, controlling for patient characteristics, volume of laboratory services, and geographic area (eTable 4 in the Supplement).

Discussion

This retrospective cohort study of commercially insured patients found that 5.9% of individuals who underwent an outpatient laboratory service in 2018 had a laboratory service billed as out of network, with a mean estimated balance bill of \$81 in addition to a \$25 observed difference in out-of-pocket payments between in- and out-of-network services. During the year, patients with an out-of-network laboratory service faced median total potential out-of-pocket spending of \$339.13 compared with \$10.51 among patients with at least 1 laboratory service but none out of network because of both to a greater volume of laboratory services and higher per-laboratory spending. Out-of-network laboratory bills affected more patients than out-of-network emergency and anesthesiology bills in all years, resulting in mean total out-of-pocket expenditures on out-of-network laboratory services that were approximately 2.5 times higher than out-of-pocket expenditures on other services in 2018.

Rates of out-of-network laboratory services varied widely across states, with 3 states having rates higher than 10%. Frequency of and trends in out-of-network laboratory services may be associated with a number of factors not captured in our data, including a lack of transparency in where laboratory samples are sent, financial incentives of physician-owned laboratory companies (eg, to order additional tests to increase charges^{15,16}), and potential consolidation among laboratory service companies.¹⁷ Financial barriers for laboratory tests may have adverse effects on patient health and finances, including avoidance of needed tests. These concerns are heightened by evidence that laboratory testing constitutes the fastest growing out-of-network spending, measured as the percentage of total spending that is out of network observed in national claims data. In comparison, the percentage of total spending that is out of network is decreasing for most other categories of services, including emergency department care and anesthesiology services.⁷ Our findings are consistent with this evidence.

Patients may face an out-of-network laboratory bill in several contexts, which creates a need for different approaches to protect them from costs when they are not aware of or able to choose where their laboratory samples are sent. They may see an in-network physician but have their laboratory samples sent out of network without their knowledge, which is analogous to the surprise bill patients might get if they go to an in-network hospital but unknowingly receive care from an

out-of-network physician. Recent legislation protects patients against surprise bills starting in 2022; federal rulemaking should ensure that laboratory testing is covered under this law.¹⁸ Patients may also face an out-of-network laboratory bill if they see an out-of-network physician. Although not the classic surprise bill case, it is unlikely that the patient chose the laboratory, and thus the service should be considered in network unless the patient actively chose an out-of-network laboratory.

Patients may receive an out-of-network laboratory bill if their insurance network does not include a laboratory with the capacity to conduct the analysis (eg, if the laboratory test is complex or rare). In this case, the patient's insurer should be responsible for any balance bill because it is the insurer's responsibility to have at least 1 in-network option for all covered laboratory tests. Finally, a patient may actively go out of network for a laboratory test (eg, for convenience). In these cases, patients may appropriately face higher costs; however, the patient should be asked to explicitly decline the in-network option.

An approach in which patients may actively decline an in-network service to seek out-of-network care is similar to a patient's choice to receive a brand-name drug when a generic option is available, which must be specified on the prescription. Operationalization of this approach would require that the claim include a record of when an in-network option was declined to charge patients more for out-of-network services. This approach would protect patients from out-of-network laboratory bills in situations in which it is unlikely they chose or were aware of where their laboratory samples were being sent while maintaining patient choice to seek out-of-network care.

Limitations

This study had several limitations. First, as in all analyses of administrative claims data, balance bills sent directly from the laboratory to the patient for costs not billed to the patient's insurance were not directly observed. This issue was mitigated by estimating balance bills based on the difference between charge and amount paid observed on the claim; however, this method may not capture the full financial burden on the patient associated with out-of-network laboratory services. The percentage of the potential balance bills that was actually paid by the patient was not observed.

Second, laboratory services that were paid fully in cash were not observed because these were not billed to insurance. Third, each laboratory service was not able to be linked to the specific physician who ordered the test because the data do not report the ordering physician. This limitation prevented the identification of surprise bills and the calculation of physician-level charges. Instead, a weighted mean of charges at the state, year, and CPT level was used, which may mask variation in charges across physicians but is designed to reflect the experience of the typical patient. Fourth, specific laboratory companies or physician offices where laboratory services were provided were not identifiable. Fifth, data were lacking on individual plan benefit design (eg, deductible amount), which may also affect out-of-pocket spending. Finally, the MarketScan data are a convenience sample of claims; they are nationally representative but

may be more representative of some services and geographic areas than others.

Conclusions

In this retrospective cohort study of a large national sample of individuals with commercial insurance who received clinical

laboratory services, out-of-network outpatient laboratory services were 5 times more common than out-of-network emergency department visits and 34 times more common than out-of-network anesthesiology services and are associated with substantial patient out-of-pocket costs. These findings suggest that there is a need to ensure that policies and regulations protect patients from financial burden associated with out-of-network laboratory services.

ARTICLE INFORMATION

Accepted for Publication: March 6, 2021.

Published Online: April 26, 2021.

doi:10.1001/jamainternmed.2021.1422

Author Contributions: Dr Sen and Mr Meiselbach had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Sen, Meiselbach, Anderson.

Acquisition, analysis, or interpretation of data:

All authors.

Drafting of the manuscript: Sen, Meiselbach, Wang, Anderson.

Critical revision of the manuscript for important intellectual content: Sen, Meiselbach, Eisenberg.

Statistical analysis: Sen, Meiselbach, Wang, Eisenberg.

Obtained funding: Anderson.

Supervision: Sen, Anderson.

Conflict of Interest Disclosures: Dr Sen reported receiving grants from Arnold Ventures during the conduct of the study. Mr Meiselbach reported receiving grants from Arnold Ventures and the Agency for Healthcare Research and Quality during the conduct of the study. Mr Wang reported receiving grants from Arnold Ventures during the conduct of the study and outside the submitted work. Dr Eisenberg reported receiving grants from Arnold Ventures during the conduct of the study. Dr Anderson reported receiving grants from Arnold Ventures during the conduct of the study.

Funding/Support: This work was supported in part by Arnold Ventures.

Role of the Funder/Sponsor: The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

REFERENCES

1. Freedman DB. Towards better test utilization: strategies to improve physician ordering and their impact on patient outcomes. *EJIFCC*. 2015;26(1):15-30.
2. Centers for Disease Control and Prevention Division of Laboratory Systems. Strengthening

Clinical Laboratories. Accessed December 3, 2020. <https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html>

3. Cooper Z, Scott Morton F. Out-of-network emergency-physician bills—an unwelcome surprise. *N Engl J Med*. 2016;375(20):1915-1918. doi:10.1056/NEJMp1608571

4. Garmon C, Chartock B. One in five inpatient emergency department cases may lead to surprise bills. *Health Aff (Millwood)*. 2017;36(1):177-181. doi:10.1377/hlthaff.2016.0970

5. Duffy EL, Adler L, Ginsburg PB, Trish E. Prevalence and characteristics of surprise out-of-network bills from professionals in ambulatory surgery centers. *Health Aff (Millwood)*. 2020;39(5):783-790. doi:10.1377/hlthaff.2019.01138

6. Chhabra KR, McGuire K, Sheetz KH, Scott JW, Nuliyalu U, Ryan AM. Most patients undergoing ground and air ambulance transportation receive sizable out-of-network bills. *Health Aff (Millwood)*. 2020;39(5):777-782. doi:10.1377/hlthaff.2019.01484

7. Song Z, Johnson W, Kennedy K, Biniek JF, Wallace J. Out-of-network spending mostly declined in privately insured populations with a few notable exceptions from 2008 to 2016. *Health Aff (Millwood)*. 2020;39(6):1032-1041. doi:10.1377/hlthaff.2019.01776

8. IBM Watson Health. IBM MarketScan Research Databases for health services researchers [Internet]. IBM Watson Health; 2019. Accessed June 19, 2020. <https://www.ibm.com/downloads/cas/6KNYVVQ2>

9. Neprash HT, Chernew ME, Hicks AL, Gibson T, McWilliams JM. Association of financial integration between physicians and hospitals with commercial health care prices. *JAMA Intern Med*. 2015;175(12):1932-1939. doi:10.1001/jamainternmed.2015.4610

10. Neprash HT, Wallace J, Chernew ME, McWilliams JM. Measuring prices in health care markets using commercial claims data. *Health Serv Res*. 2015;50(6):2037-2047. doi:10.1111/1475-6773.12304

11. Chen JL, Hicks AL, Chernew ME. Prices for physician services in Medicare Advantage versus traditional Medicare. *Am J Manag Care*. 2018;24(7):341-344.

12. Chhabra KR, Sheetz KH, Nuliyalu U, Dekhne MS, Ryan AM, Dimick JB. Out-of-network bills for privately insured patients undergoing elective surgery with in-network primary surgeons and facilities. *JAMA*. 2020;323(6):538-547. doi:10.1001/jama.2019.21463

13. Sun EC, Mello MM, Moshfegh J, Baker LC. Assessment of out-of-network billing for privately insured patients receiving care in in-network hospitals. *JAMA Intern Med*. 2019;179(11):1543-1550. doi:10.1001/jamainternmed.2019.3451

14. Elixhauser A, Steiner C, Harris DR, Coffey RM. Comorbidity measures for use with administrative data. *Med Care*. 1998;36(1):8-27. doi:10.1097/00005650-199801000-00004

15. Schulte F. An out-of-network lab, an elaborate urine test, and then a surprise bill. Shots (NPR) [serial on the Internet]. February 16, 2018. Accessed June 19, 2020. <https://www.npr.org/sections/health-shots/2018/02/16/585548181/an-out-of-network-lab-an-elaborate-urine-test-and-then-a-surprise-bill>

16. Harris R. For her head cold, insurer coughed up \$25,865. Shots (NPR) [serial on the Internet]. December 23, 2019. Accessed June 19, 2020. <https://www.npr.org/sections/health-shots/2019/12/23/787403509/for-her-head-cold-insurer-coughed-up-25-865>

17. Fong T. The PAMA effect: consolidation of clinical labs expected as legislation set to take effect. 360Dx [serial on the Internet]. May 30, 2017. Accessed June 19, 2020. <https://www.360dx.com/regulatory-news/pama-effect-consolidation-clinical-labs-expected-legislation-set-take-effect>

18. Adler L, Fiedler M, Ginsburg PB, Hall M, Ippolito B, Trish E. Understanding the No Surprises Act. USC-Brookings Schaeffer Initiative for Health Policy. February 4, 2021. Accessed June 19, 2020. <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/02/04/understanding-the-no-surprises-act/>