

will impact COLA laboratories (6,881 laboratories, 4 percent) when COLA revises its requirements to be equivalent to this final rule. Laboratories accredited by organizations other than COLA currently have QC requirements that are more stringent than those under the CLIA QC phase-in. With the adoption of the requirements in this final rule, CLIA requirements will more closely resemble these accrediting organizations' standards for QC.

Therefore, we estimate that these QC changes will immediately affect 29,601 laboratories (17 percent of the Nation's laboratories). These laboratories consist of those with a Certificate of Compliance (22,720) and COLA-accredited (6,881) laboratories. The 22,720 Certificate of Compliance laboratories that this QC change may affect consist of 1,392 Hospital (6 percent of laboratories with a Certificate of Compliance), 2,593 Independent (11 percent), 14,687 physician office

laboratories (POLs) (65 percent), and 4,048 Other (18 percent) laboratories (Table 3). Since the majority of COLA laboratories are POLs (95 percent, COLA estimate), we assume all COLA laboratories are POLs for this analysis. The estimated total number of POLs that these QC changes will impact is 21,568, which comprise the largest portion of the 29,601 laboratories (73 percent) we estimated will be affected by this regulation. However, the affected POLs constitute only 22 percent of all U.S. POLs and 12 percent of all laboratories in the country. The vast majority (77 percent) of POLs hold Certificates of Waiver or PPM. In addition, changes in this final rule will not immediately affect most U.S. hospital laboratories because they are typically accredited, rather than Certificate of Compliance laboratories. The additional laboratory types in the CMS OSCAR (2001) database classified as "Independent," are typically referral testing sites, and

"Other" laboratories generally perform testing at a variety of healthcare sites including home health testing and nursing homes.

Although the percentages of laboratories with each certificate type remained relatively stable over the past several years, the absolute numbers show trends toward lower complexity certificates (waiver and PPM). For example, from 1998 to 2001, the number of laboratories with Certificates of Compliance decreased by 20 percent (5,604), and an increase occurred for both Waiver (+9 percent; 7,628) and PPM (+12 percent; 3,988) laboratories (Table 4). We expect this trend to continue in the future because of the widening availability of waived tests, many of which are considered important for on-site testing in POLs. Therefore, the long-term impact of this regulation may be mitigated by this continuing decrease in the number of Certificate of Compliance laboratories.

TABLE 3.—CERTIFICATE TYPE BY LABORATORY TYPE

Laboratory type ⁵	Certificate type ¹										
	Compliance		Waiver		Accreditation		PPM				
	N ²	% ³	N	%	N	%	N	%	State exempt ⁴		All
									N	%	N
Hospital	1,392	15	1,231	14	5,475	62	224	3	498	6	8,820
Independent	2,593	51	910	18	937	18	131	3	515	10	5,086
Physician Office	14,687	15	42,927	44	6,416	7	31,510	33	1,391	1	96,931
Other	4,048	7	46,472	76	3,296	5	6,439	10	3,764	2	64,019
All	22,720	13	91,540	53	16,124	10	38,304	22	6,168	2	174,856

¹OSCAR, 2001.

²Number of Laboratories.

³Column Percent.

⁴Data from NY and WA States.

⁵Self Reported.

TABLE 4.—CHANGES IN CERTIFICATE TYPE, 1998 TO 2001

Certificate type ¹	1998		1999		2000		2001	
	N ²	% ³	N	%	N	%	N	%
Compliance	28,324	17	27,819	16	25,145	15	22,720	13
Waiver	83,912	52	87,754	52	89,998	52	91,540	54
Accreditation	16,469	10	17,337	10	15,885	9	16,124	10
PPM	34,316	21	36,789	22	37,535	22	38,304	22
All	163,021	100	169,700	100	171,736	100	171,010	100

¹OSCAR, 2001.

²Number of Laboratories.

³Column Percent.

Specific Impact Dependent on Test Volume and Laboratory Type

Certificate of Compliance laboratories comprise 13 percent of U.S. laboratories and perform 991 million (19 percent) of the 5.3 billion tests annually in the U.S. (OSCAR, 2001). Our estimate of 5.3 billion tests for the year 2001 is consistent with the estimate of 5.9

billion tests for 1996 by Hoerger, Eggleston, Lindrooth and Basker (1997) and the estimate of 5.7 billion tests for the year 2000 in an Institute of Medicine report (Institute of Medicine, 2000). The average annual test volume per Certificate of Compliance laboratory is 43,618; however, the test volume distribution is skewed. Most (69

percent) Certificate of Compliance laboratories perform less than 10,000 tests per year, with 42 percent performing less than 2,000. For COLA laboratories, the average annual test volume is approximately 5,000 tests per laboratory (COLA, personal communication, June 2001), making the aggregate annual test volume for all