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Chapter 449@ Medical and Other Related Facilities

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Section 449.999465@ Scope of violations: Evaluation of representative sample of recipients; sample size

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1.

In determining the scope of a violation, an inspection of an outpatient facility must evaluate a representative sample of patients as provided in this section. Unless a sample of a different size is required for the inspection by federal law, the sample must consist of at least the following size: Number of patients offered a service of general anesthesia, conscious sedation or deep sedation Minimum number of such patients in sample 1 -

9.....	All patients	10 -
40.....	10	41 -
75.....	15	76 -
100.....	20	101 -
175.....	25	176 -
250.....	30	251 -
350.....	35	351 -
450.....	40	451 or
more.....	50	

2.

The sample size used in identifying the scope of a deficiency in a subsequent inspection conducted to evaluate compliance with a plan of correction must not be

less than 60 percent of the sample size used in the initial inspection.

3.

In determining the scope of a violation involving particular kinds of care, treatment or services, the inspection must evaluate a representative sample of patients receiving or requiring the particular kinds of care, treatment or services. Unless a sample of a different size is required for the inspection by federal law, the sample must consist of at least the following size:

Number of patients needing or receiving a particular kind of care, treatment or services	Minimum number of such patients in sample
1 - 9.....	1

All patients 10 - 40.....	10	41
- 75.....	15	76 -
100.....	20	101 -
175.....	25	176 -
250.....	30	251 -
350.....	35	351 -
450.....	40	451 or
more.....	50	

4.

The Bureau may review more than the minimum number of patients. If it does so, the determination of scope must be based on the number of patients actually reviewed.

5.

If the Bureau investigates a complaint relating to a patient, the Bureau may sample only that patient. The scope of any deficiency cited pursuant to this subsection must be scope level one.

6.

As used in this section, "patient" means a person who was offered a service of general anesthesia, conscious sedation or deep sedation at the outpatient facility within the 30 days immediately preceding the date the Bureau inspects the outpatient facility.