

**INSTRUCTIONS FOR COMPLETING DISCLOSURE OF
OWNERSHIP AND CONTROL INTEREST STATEMENT (FORM 1513)**

SPECIAL INSTRUCTIONS FOR CLIA LABORATORIES

All CLIA laboratories must complete Part I through Part VII(b) of this form. Failure to submit requested information may result in the suspension or revocation of any CLIA certificate or denial of application for prospective laboratories.

GENERAL INSTRUCTIONS

For definitions, procedures, and requirements, refer to the appropriate Regulations:

CLIA	-42CFR 493
Title XVIII	-42CFR 420 200-206
Title XIX	-42CFR 455 100-106
Title XX	-45CFR 228 72-73

Please answer all questions as of the current date. If the yes block for any item is checked, list requested additional information under the Remarks Section, referencing the item number to be continued. If additional space is needed use an attached sheet.

Return the original to the State agency, retain a copy for your files.

This form is to be completed upon request. Any substantial delay in completing the form should be reported to the State survey agency.

DETAILED INSTRUCTIONS

These instructions are designed to clarify certain questions on the form. Instructions are listed in question order for easy reference. No instructions have been given for questions considered self-explanatory.

IT IS ESSENTIAL THAT ALL APPLICABLE QUESTIONS BE ANSWERED ACCURATELY AND THAT ALL INFORMATION BE CURRENT.

Item I - Under identifying information specify in what capacity the entity is doing business as (DBA), for example, name of trade or corporation.

Item II-Self-explanatory.

Item III- For CLIA purposes, list the names of all individuals and organizations having direct or indirect ownership interest, or controlling interest in the disclosing entity.

Direct ownership interest is defined as the possession of stock, equity in capital or any interest in the profits of the disclosing entity. A disclosing entity is the entity that is providing laboratory services.

Indirect ownership interest is defined as ownership interest in an entity that has direct or Indirect ownership interest in the disclosing entity.

Controlling interest is defined as the operational direction of management of a disclosing entity which may be maintained by any or all of the following devices: the ability or authority, expressed or reserved, to amend or change the corporate Identity (i.e., joint venture agreement, unincorporated business status) of the disclosing entity; the ability or authority to nominate or name members of the Board of Directors or Trustees of the disclosing entity, the ability or authority, expressed or reserved, to amend or

change the by-laws, constitution, or other operating or management direction of the disclosing entity; the right to control any or all of the assets or other property of the disclosing entity upon the sale or dissolution of that entity; the ability or authority, expressed or reserved, to control the sale or any of all of the assets, to encumber such assets by way of mortgage or other indebtedness to dissolve the entity, or to arrange for the sale or transfer of the disclosing entity to new ownership or control.

Items IV-VII - Changes in Status

Change in status is defined as any change in management control. Examples of such change would include: a change in Director, a change in the composition of the owning partnership which under applicable State law is not considered a change in ownership, or the hiring or dismissing of any employees with any financial interest in the facility or in an owning corporation, or any change of ownership, or contracting the operation of the facility to a management corporation or changing management corporations.

For Items IV-VII, if the yes box is checked, list additional information requested under Remarks. Clearly identify which item is being continued.

Item IV - (a & b) If there has been a change in ownership within the last year or if you anticipate a change, indicate the date in the appropriate space.

Item V - If the answer is yes, list the name of the management firm and employer identification number (EIN) or the name of the leasing organization. A management company is defined as any organization that operates and manages a business on behalf of the owner of that business, with the owner retaining ultimate legal responsibility for operation of the facility.

Item VI - If the answer is yes, provide the date the change was made. Be sure to include the name of the new Director.

Item VII - A chain affiliate is any free-standing health care facility that is either owned, controlled, or operated under lease or contract by an organization consisting of two or more free-standing health care facilities organized within or across State lines which is under the ownership or through any other device, control, and direction of a common party. Chain affiliates include such facilities whether public, private, charitable, or proprietary. They also include subsidiary organizations and holding corporations.