



**Indiana  
Department  
of  
Health**



INDIANA  
STATE ETHICS COMMISSION

Eric J. Holcomb  
Governor

Kristina M. Box, MD, FACOG  
State Health Commissioner

**IC 4-2-6-11**

**Post-employment waiver**

JUN 10 2021

FILED

As the Appointing Authority of Indiana Department of Health, I am filing this waiver of the application of the Code of Ethics' post-employment restriction as it applies to Lynette Smith in her post-employment with a LabCorp laboratory in South Bend, Indiana.

I understand that I must file and present this waiver to the State Ethics Commission at their next available meeting. I further understand that this waiver is not final until approved by the State Ethics Commission.

A. This waiver is provided pursuant to IC 4-2-6-11(g) and specifically waives the application of  
*(Please indicate the specific restriction in 42 IAC 1-5-14 (IC 4-2-6-11) you are waiving):*

IC 4-2-6-11(b)(1): 365 day required "cooling off" period before serving as a lobbyist.

IC 4-2-6-11(b)(2): 365 day required "cooling off" period before receiving compensation from an employer for whom the state employee or special state appointee was engaged in the negotiation or administration of a contract and was in a position to make a discretionary decision affecting the outcome of such negotiation or administration.

IC 4-2-6-11(b)(3): 365 day required "cooling off" period before receiving compensation from an employer for which the former state employee or special state appointee made a directly applicable regulatory or licensing decision.

IC 4-2-6-11(c): Particular matter restriction prohibiting the former state employee or special state appointee from representing or assisting a person in a particular matter involving the state if the former state officer, employee, or special state appointee personally and substantially participated in the matter as a state worker. *(Please provide a brief description of the specific particular matter(s) to which this waiver applies below):*

To promote, protect, and improve the health and safety of all Hoosiers.



It is possible, but not likely that Mrs. Smith may be asked by LabCorp to assist LabCorp with determinations or enforcement proceedings involving other LabCorp laboratories she previously surveyed and/or made regulatory decisions.

- B. IC 4-2-6-11(g)(2) requires that an agency's appointing authority, when authorizing a waiver of the application of the post-employment restrictions in IC 4-2-6-11(b)-(c), also include specific information supporting such authorization. Please provide the requested information in the following five (5) sections to fulfill this requirement.
1. Please explain whether the employee's prior job duties involved substantial decision-making authority over policies, rules, or contracts:

Mrs. Smith's duties as a Medical Surveyor III does not involve substantial decision-making authority over policies, rules, or contracts. That authority is the primary responsibility of the Centers for Medicare and Medicaid Services (CMS); the Acute and Continuing Care Division Director; and the Indiana Director of Food Protection Division.

Mrs. Smith has not promulgated any rules. She does make decisions regarding a facility's compliance with CLIA regulations, outpatient physical therapy regulations, portable x-ray regulations, hospital rules and regulations, ambulatory surgery center rules and regulations, blood center rules, and the Indiana Food Code. Mrs. Smith has no enforcement authority. That authority is the primary responsibility of CMS. Mrs. Smith also participates in the review of Plans of Correction and Allegations of Compliance, but decisions of a plan's acceptability is not made solely by Mrs. Smith. The decision is a team effort between the surveyor, quality review medical surveyor, the program manager, and sometimes the CMS consultant. As an accredited laboratory, Mrs. Smith has not made a prior compliance decision for the LabCorp laboratory at the South Bend, Indiana location (CLIA number 15D2171417). Additionally, Mrs. Smith's potential employment with LabCorp will only involve the South Bend, Indiana laboratory with the CLIA number 15D2171417.

Although Mrs. Smith has not made any regulatory decisions that applied to the specific LabCorp laboratory at which she intends to work, she has surveyed and made regulatory decisions for three other LabCorp-owned laboratories. Because the restriction applies to the employer (and its parent or subsidiary) and not



individual facilities, she would be prohibited from accepting employment from LabCorp and working for any LabCorp facility until the cooling off period expires.

2. Please describe the nature of the duties to be performed by the employee for the prospective employer:

Some duties Mrs. Smith will perform in her new position with LabCorp include:

- Managing the day-to-day operations of the accredited laboratory (CLIA number 15D2171417 only).
- Provide oversight and support to a team of supervisors and laboratory staff (CLIA number 15D2171417 only).
- Monitor and manage productivity of the laboratory (CLIA number 15D2171417 only).
- Monitor staffing models and address inefficiencies for laboratory (CLIA number 15D2171417 only).
- Monitor customer satisfaction for laboratory (CLIA number 15D2171417 only).

3. Please explain whether the prospective employment is likely to involve substantial contact with the employee's former agency and the extent to which any such contact is likely to involve matters where the agency has the discretion to make decisions based on the work product of the employee:

Mrs. Smith is not likely to have substantial contact with ISDH in her role as the Laboratory Manager at LabCorp (CLIA number 15D2171417). LabCorp is accredited by the College of American Pathologists (CAP) and is routinely surveyed by its accrediting body, and not ISDH surveyors. Additionally, Mrs. Smith would only be responsible for the LabCorp laboratory located in South Bend, Indiana (CLIA number 15D2171417) and would not participate in a CLIA survey conducted by ISDH at another location or CLIA number. However, potential future contact with ISDH may involve a validation survey performed by ISDH at the LabCorp laboratory in South Bend, Indiana. This contact with Mrs. Smith would be limited, as the majority of the survey activities would involve review of information provided by the laboratory's supervisory staff and not Mrs. Smith. Mrs. Smith's role as the laboratory manager would be to ensure the survey team receives the information needed from the supervisory staff and



report any compliance related issues to LabCorp's director of operations. Currently, only about 2% of the laboratories accredited by CAP are surveyed each year nationwide. Validations surveys are typically performed as a "lookback," no more than three months after the CAP survey was performed. The LabCorp laboratory in South Bend (CLIA # 15D2171417) received their last CAP survey in October of 2020. Since CAP surveys are performed approximately every two years, the next CAP survey would be scheduled for the fall of 2022. If this lab is chosen for a validation survey, it would not occur prior to fall of 2022, which would be greater than 365 days post-employment for Mrs. Smith. Therefore, the likelihood of LabCorp in South Bend receiving a validation survey is low and if it should receive a validation survey, Mrs. Smith's involvement in the survey would be limited. Additionally, Mrs. Smith would not be involved in the compliance decision making by ISDH surveyors, nor has she been involved with compliance decision making for the LabCorp lab in South Bend (CLIA number 15D2171417) in the past. Other potential contact may be made if ISDH needs to be contacted to make certain changes (such as demographic information) on the CLIA certificate. This contact would not involve regulatory decision making and any changes would be required to be approved by the LabCorp laboratory director. Mrs. Smith would simply be the person to provide the documentation to ISDH for the change.

4. Please explain whether the prospective employment may be beneficial to the state or the public, specifically stating how the intended employment is consistent with the public interest:

Mrs. Smith's employment with LabCorp would be beneficial to the state and public because she has knowledge of quality assessment, performance improvement, good laboratory practices, and CLIA regulations. She is also knowledgeable in laboratory processes and with her knowledge. Mrs. Smith will be able to:

- Improve the quality of LabCorp's laboratory testing for the public.
- Help the LabCorp focus on continuous performance improvement of all laboratory tests offered.
- Increase LabCorp's understanding of regulatory compliance.
- Provide insight on CLIA and public health concerns with regards to SARS-CoV-2 testing.



- Educate laboratory staff about the importance of compliance with rules and regulations and maintaining that compliance.
- Continue to promote and provide essential public health services, in the form of quality laboratory testing, consistent with the mission of ISDH.

5. Please explain the extent of economic hardship to the employee if the request for a waiver is denied:

Denying this waiver would provide a substantial economic hardship for Mrs. Smith's family and future. The prospective employer offers significantly more in compensation and provides a stable employment position. In addition, the professional growth offered by the prospective employer could potentially help the State and public health, considering Mrs. Smith's expertise in laboratory testing, quality assessment, performance improvement, and regulatory compliance.

C. Signatures

1. Appointing authority/state officer of agency

By signing below, I authorize the waiver of the above-specified post-employment restrictions pursuant to IC 4-2-6-11(g)(1)(A). In addition, I acknowledge that this waiver is limited to an employee or special state appointee who obtains the waiver before engaging in the conduct that would give rise to a violation.

Kristina Box, MD, FACOG  
State Health Commissioner

DATE



2. Ethics Officer of agency

By signing below, I attest to the form of this waiver of the above-specified post-employment restrictions pursuant to IC 4-2-6-11(g)(1)(B).

Deana M. Smith  
Deana M. Smith

5/27/2021  
DATE

D. Approval by State Ethics Commission

|  |                |
|--|----------------|
| <b>FOR OFFICE USE ONLY</b>                     |                |
| Approved by State Ethics Commission            |                |
| <u>[Signature]</u>                             | <u>6-10-21</u> |
| Katherine Noel, Chair, State Ethics Commission | Date           |

**Mail to:**  
Office of Inspector General  
315 West Ohio Street, Room 104  
Indianapolis, IN 46202  
OR  
**Email scanned copy to:**  
[info@lg.in.gov](mailto:info@lg.in.gov)  
*Upon receipt you will be contacted*