California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

STANDARD OF CARE COMMITTEE CHAIR REPORT

Seung Oh, Licensee Member, Chairperson
Maria Serpa, Licensee Member, Vice-Chairperson
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Jessica Crowley, Licensee Member
Nicole Thibeau, Licensee Member

During the members, members will review a summary of the Committee's work at its October 25, 2022, meetings as well as updated for discussion and action as necessary.

a. Discussion and Consideration of Results of Pharmacy Survey Related to Current Practice and Possible Movement to Standard of Care Enforcement model

Relevant Law
Business and Professions Code Section 4301.3 requires the Board to convene a workgroup of interested stakeholder to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussion through a report as specified.

For Committee Discussion and Consideration
During its last meeting, members discussed that not all licensees are available to participate in public meetings scheduled and determined it appropriate to develop and release of a survey of California licensed pharmacists is appropriate as another means of soliciting feedback for the Committee's future consideration.
The Committee discussed the basic framework for the survey questions. Following the meeting President Oh finalized the survey questions with staff. Prior to release the questions were also reviewed and changes incorporated as recommended by DCA staff with expertise in survey design.

The survey was available September 12 through October 3 with subscriber alerts released during the survey period. The Board received 1,788 responses. Ninety-eight percent of the respondents indicated they are currently licensed in California and eighty-seven percent indicated they are actively practicing

as a pharmacist. Responses were received from a variety of practice settings including:

- 46.5% community pharmacy
- 23% hospital pharmacy
- 8.5% ambulatory care
- 22% other (including academia, pharmacy benefit managers, compounding, administration, closed door, mail order, etc.)

For Committee Consideration and Discussion

During the meeting members will have an opportunity to review the survey results which hopefully provide another dataset for members to consider as part of its evaluation about whether the Board should recommend a more robust use of a standard of care enforcement model.

Attachment 1 includes presentation slides providing summary information on survey responses.

b. Discussion and Consideration of Policy Questions Related to Standard of Care Enforcement Model in the Practice of Pharmacy

Background

Consistent with the provisions of section 4301.1, the Board established a Standard of Care Ad Hoc Committee to establish a means for members and stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy. The Legislature never defined how it interpreted a standard of care enforcement model.

As part of the Committee's first meeting, all interested parties were provided with an opportunity to present on the topic. In addition, participants received a joint presentation by counsel from DCA and the Office of the Attorney General regarding legal issues associated with a standard of care and what that model entails.

Members have been advised that the Board's enforcement model is a hybrid model including the potential for discipline based on violations of specific California or federal law and for violations of standard of care in general.

As an example, under state and federal law, a pharmacist must exercise corresponding responsibility; however, the law does not detail out the specific actions a pharmacist must take when fulfilling this responsibility. Court and Board cases have established certain red flags that should guide pharmacists in exercising this statutory responsibility, however, there is not a checklist of required actions that would constitute compliance with this duty. Rather, the

discipline cases are fact specific and could also involve breaches of standard of care – i.e., what a reasonable pharmacist would do under the fact pattern presented. Although the legal requirements have long existed, the board has dedicated significant to time educating licensees about their obligations.

In contrast, as another example, California Code of Regulations Section 1707.2 provides that a pharmacist is required to provide patient consultation in all settings under specified conditions including, 1)upon request; 2) **whenever the pharmacist deems it warranted in the exercise of his or her professional judgement**; 3) whenever the prescription drug has not previously been dispensed; 4) whenever the prescription drug has not previously dispensed to a patient in the same dosage from, strength or with the same written directions, is dispensed by the pharmacy. In this scenario, there are bright line rules established as well as requirements for use of professional judgement.

Throughout these meetings members have also received significant comments about current pharmacist patient care services outside of the traditional dispensing role of pharmacists. The expanded patient care role of a pharmacist has resulted in improved patient access and patient outcomes. Presentations provided highlight the benefits to patients and the healthcare system. Many commenters have stated that they view the standard of care model as a means to expand a pharmacist's scope of practice rather than being bound by protocols and other detailed requirements for a pharmacist to provide patient care (i.e., provision of PEP and PrEP, hormonal contraceptives, smoking cessation and other areas that permit pharmacists within specific confines to provide certain care directly to a patient without reliance on a physician prescription).

These conversations are noteworthy as they demonstrate the benefit of pharmacist-driven patient care; however, they may not be related to the topic before the Board which is to consider whether moving to a standard of care enforcement **model** would be feasible and appropriate for the regulation of pharmacy. In order to provide a report to the Legislature, we suggest that the Committee and then the Board focus on defining a standard of care enforcement model and answer questions regarding their views of whether it would be appropriate to change the current disciplinary process to *solely* a standard of care model or whether the existing hybrid model should be retained. We then suggest that the Committee consider the other comments whether movement to a standard of care model for pharmacists might be appropriate and feasible in determining their scope of practice.

<u>For Committee Consideration and Discussion</u>

During the meeting members and stakeholders will have the opportunity to consider the legislative mandate regarding whether it is feasible and appropriate to move to standard of care enforcement model. It is recommended that the Committee concentrate first on the appropriateness of any such change and consider feasibility if it determines that movement or change is appropriate.

As part of the discussion, it is recommended that the comments focus on consideration of the question through the lens of the Board's consumer protection mandate as reflected in Business and Professions Code section 4001.1 that states that "[w]henever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public should be paramount." Because a report is being prepared for the Legislature to consider, we still believe it is proper to identify other interests but also any safety issues that could enable the Legislature to do any required weighing of competing interests.

1. With the understanding of the Board's current enforcement model approach that is a hybrid model, does the Committee believe that changing the current structure is appropriate for facilities, including pharmacies, wholesale distributors, 3PLs or other facilities licensed by the Board
    a. For example, does the Committee believe that an enforcement action should only be allowed against a facility for a violation of standard of care by a pharmacist even if a specific federal or state statute or rule is violated?
    b. Does the Committee as a theoretical matter believe that disciplinary actions against facility licensees could continue to be predicated on either violation of a specific State or federal statute or rule?
    c. If yes, does the Committee believe that changes to some of the prescriptive statutes and regulations should be changed or modernized?
2. Does the Committee believe a standard of care enforcement model is feasible and appropriate in the regulation of pharmacy personnel excluding pharmacists (i.e., designated representatives, pharmacy interns, and/or pharmacy technicians)?
    a. For example, if a violation of cold chain storage requirements is found at a wholesale distributor, does the Committee believe that a disciplinary action against the designated representative responsible for compliance with federal and state requirements should be subject to discipline for the violation of the specific requirement?
    b. Pharmacy technicians currently operate under the direction and supervision of pharmacists.

3. **Pharmacists**—does the Committee believe that pharmacists and PICs should continue to face potential discipline for violations of state or federal statutes and/or standard of care breaches or only if a pharmacist breaches a standard of care?
    a. For example, a pharmacist dispenses a Schedule II controlled substance that was not on the correct prescription as required under Health & Safety Code. Should the pharmacist face potential discipline for the breach of H&SC provision or should testimony about what other pharmacists handle such prescriptions be enough to counter a violation of this statute.
    b. Does this analysis change by setting – i.e., retail chains versus hospitals?
4. Many commenters suggested that a standard of care enforcement model meant expanding a pharmacist's scope of practice by using a standard of care model rather than prescriptive requirements when pharmacists are exercising clinical judgment as opposed to their traditional dispensing role.
    a. Does the Committee believe that there are specific provisions included in a pharmacist's scope of practice that require compliance with specific pharmacy statutory provisions or regulations that would be appropriate to consider replacing with a standard of care (e.g., naloxone, travel medicines, PEP/PrEP etc.? If yes, which ones)?
    b. Does the Committee believe that the practice setting makes a difference in this analysis?
5. Does the Committee believe an expanded use of a standard of care model for scope of practice could expand access to care or improves patient outcomes?
    a. Does the Committee believe that setting minimum requirements on training or education or requirements to ensure baseline competence across the State is preferable or to allow for deviations based on geography, size of practice or other variables?
6. Does the Committee believe that under current working conditions, a transition to more expanded scope of practice is possible and appropriate? If so, under what conditions?
7. If the Committee believes that expanding some pharmacist clinical duties by using a standard of care model is appropriate, does the Committee believe it is appropriate to allow a business to develop policies and procedures for pharmacist to follow, or could such practice impede a pharmacist's ability to exercise professional judgement?
    a. For instance, should patient care policies be required to be developed by the PIC or merely approved by PIC?
    b. Could practice setting impact the power that the pharmacist has in setting appropriate patient care responses if scope of practice is expanded by standard of care model.

8. In light of the survey responses provided, does the Committee believe steps need to be taken to ensure pharmacists are empowered to provide appropriate patient care versus policies and procedures developed by corporations or business entities that would dictate patient care?
    a. How does Board ensure that patient care policies are being developed by licensed pharmacists?
    b. If the Committee believes that moving scope of practice to a standard of care model is appropriate for all settings, does it believe, similar to the Medical Practice Act, that there should be a bar on the corporate practice of pharmacy?
9. What aspects of pharmacist's practice, if any, does the Committee believe should not transition to an expanded standard of care enforcement model, (e.g., compounding)?
    a. For example, does the Committee believe that a potential expansion of scope of practice should be limited by setting or limited to clinical practice (i.e., pharmacists providing direct patient care outside of their traditional dispensing role)
10. Does the Committee believe, as part of its report to the Legislature, expansion of the scope of practice for pharmacists is appropriate? If so, how and in what areas?

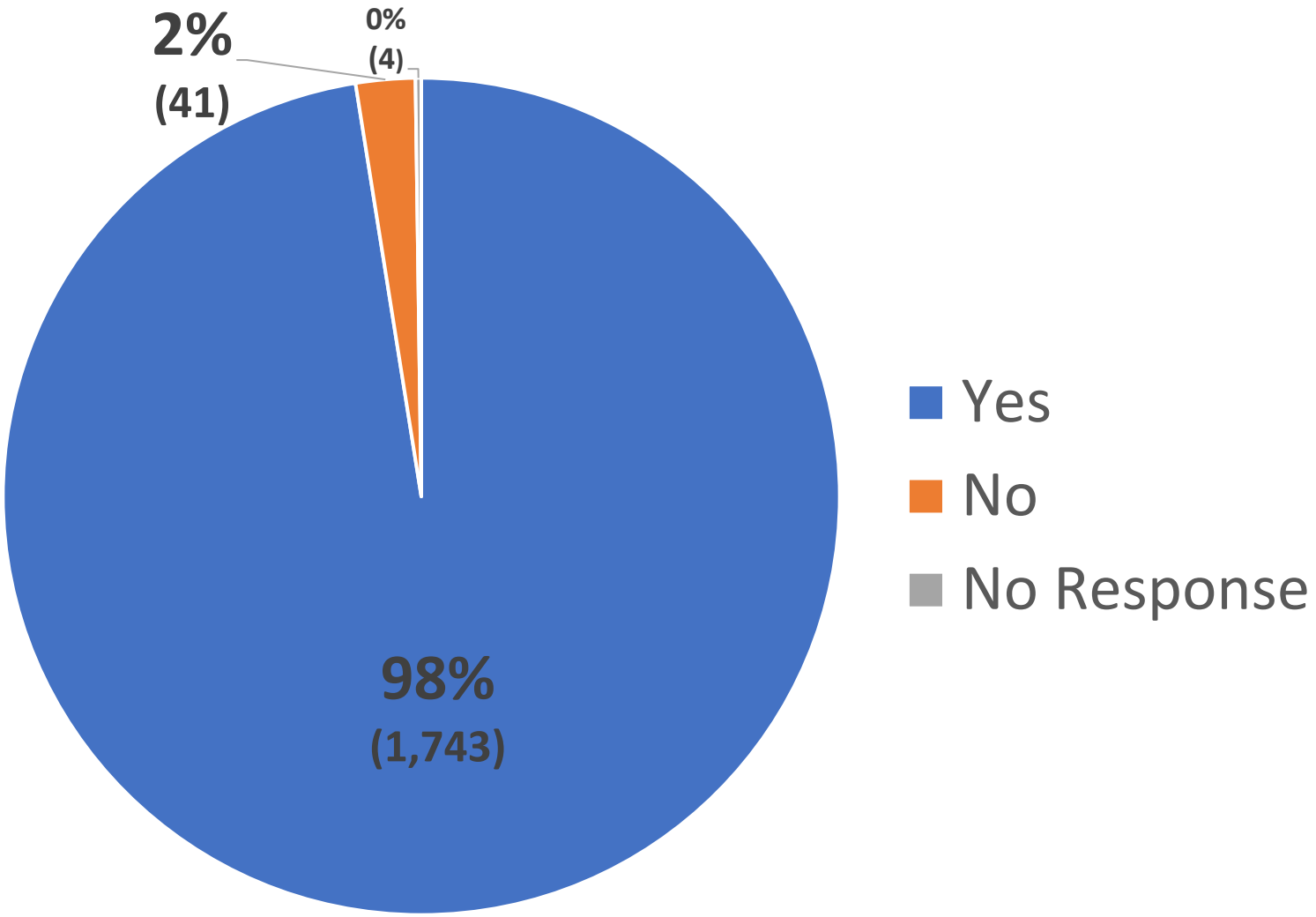
Attachment 1

Standard of Care Survey

CA Board of Pharmacy

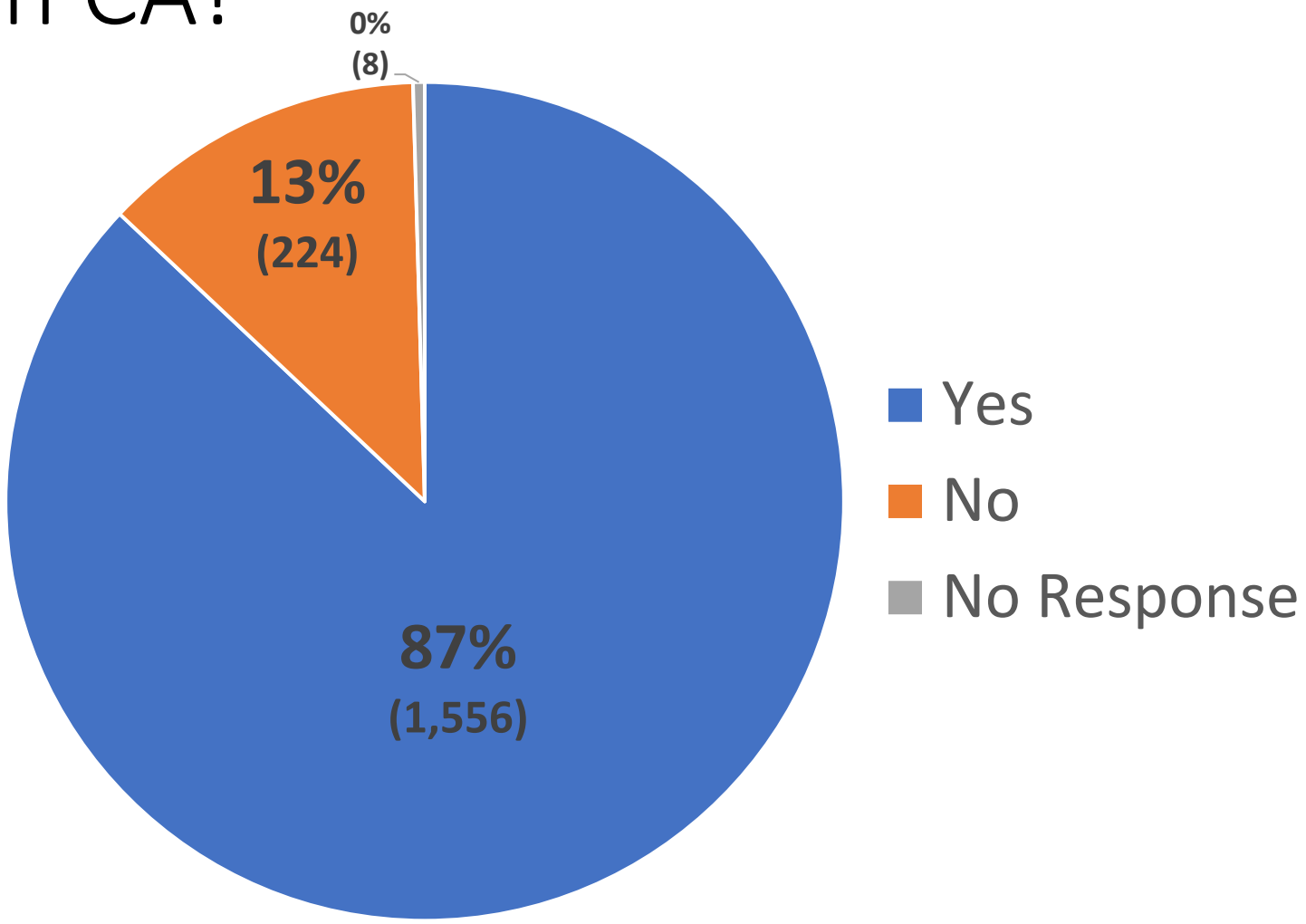
Department of Consumer Affairs

Q1 Are you currently licensed as a pharmacist in CA?



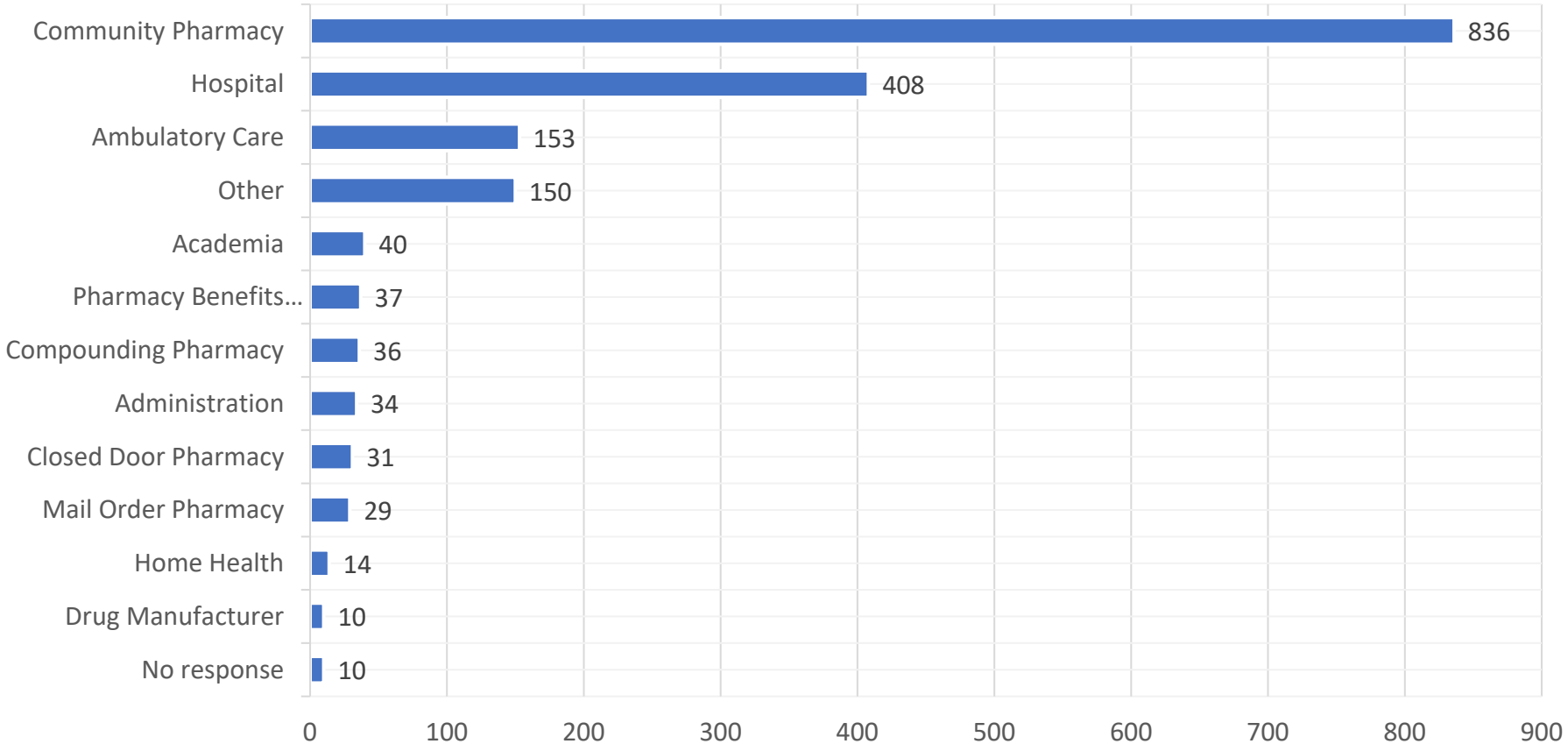
Total Respondents: 1,788

Q2 Are you currently actively practicing as a pharmacist in CA?



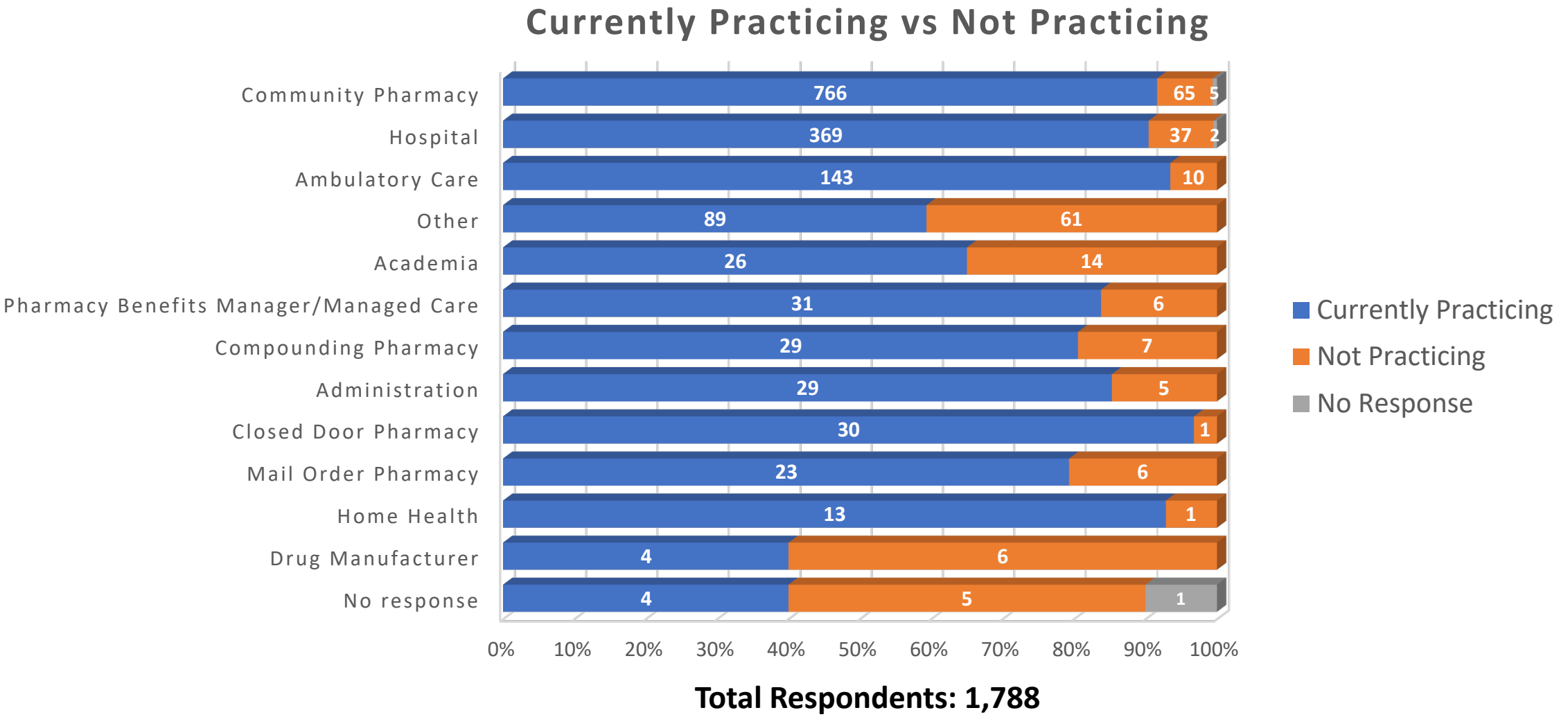
Total Respondents: 1,788

Q3 Which of the following best describes your practice setting?



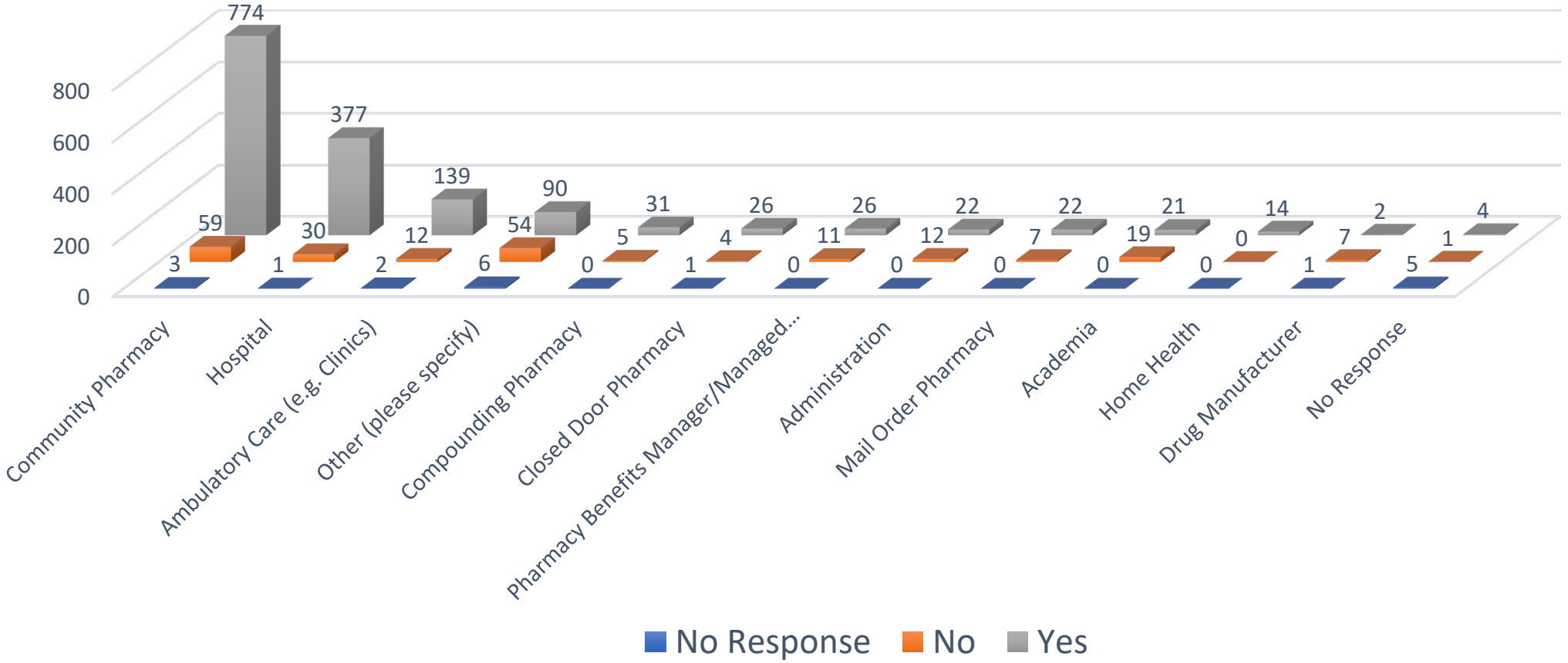
Total Respondents: 1,788

Q3 Which of the following best describes your practice setting?



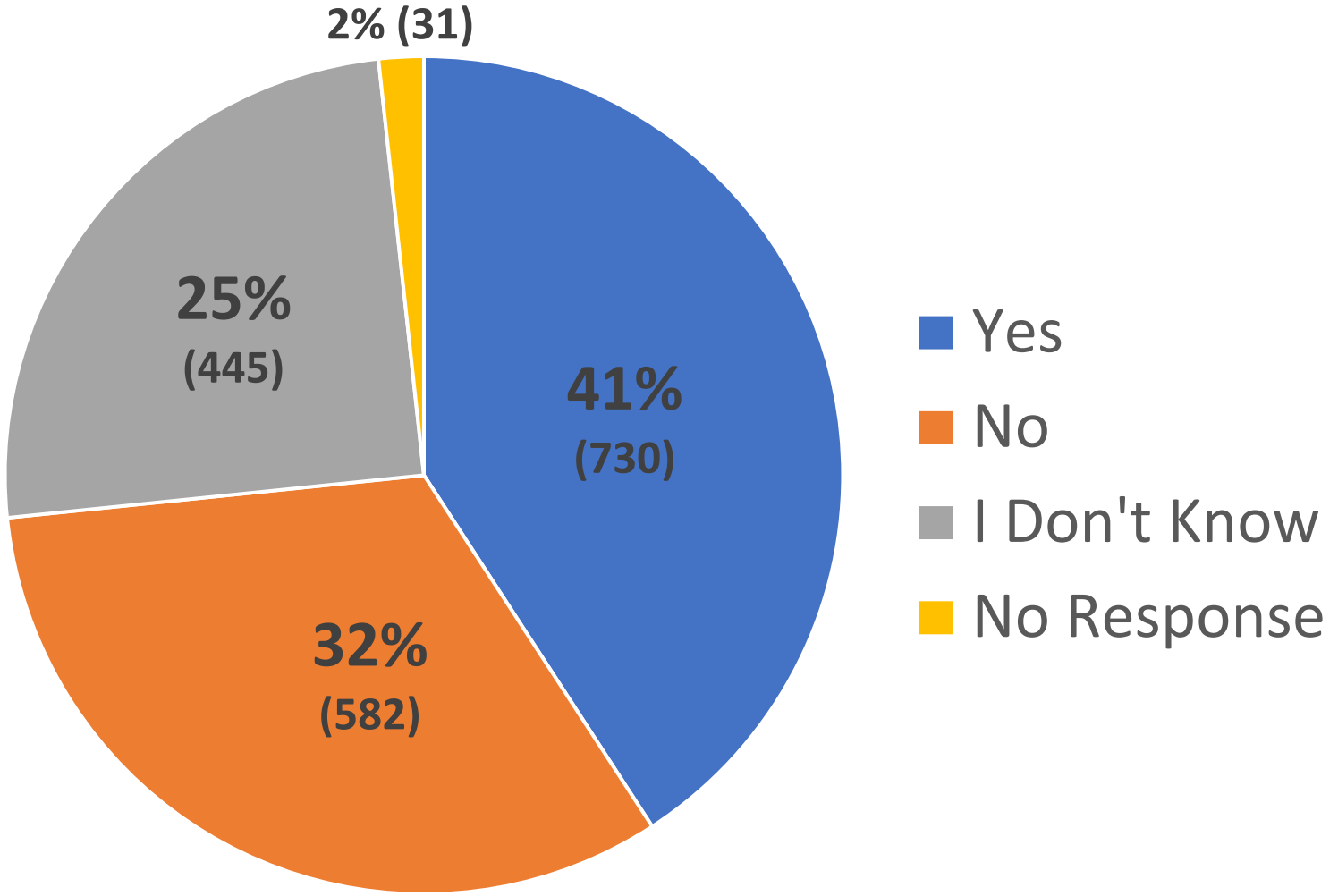
Total Respondents: 1,788

Q4 In your practice, do you provide patient care services (included but not limited to dispensing, MTM, drug monitoring, and other clinical services)?



Total Respondents: 1,788

Q5 Do you believe there are additional functions that should be added to a pharmacist's scope of practice?



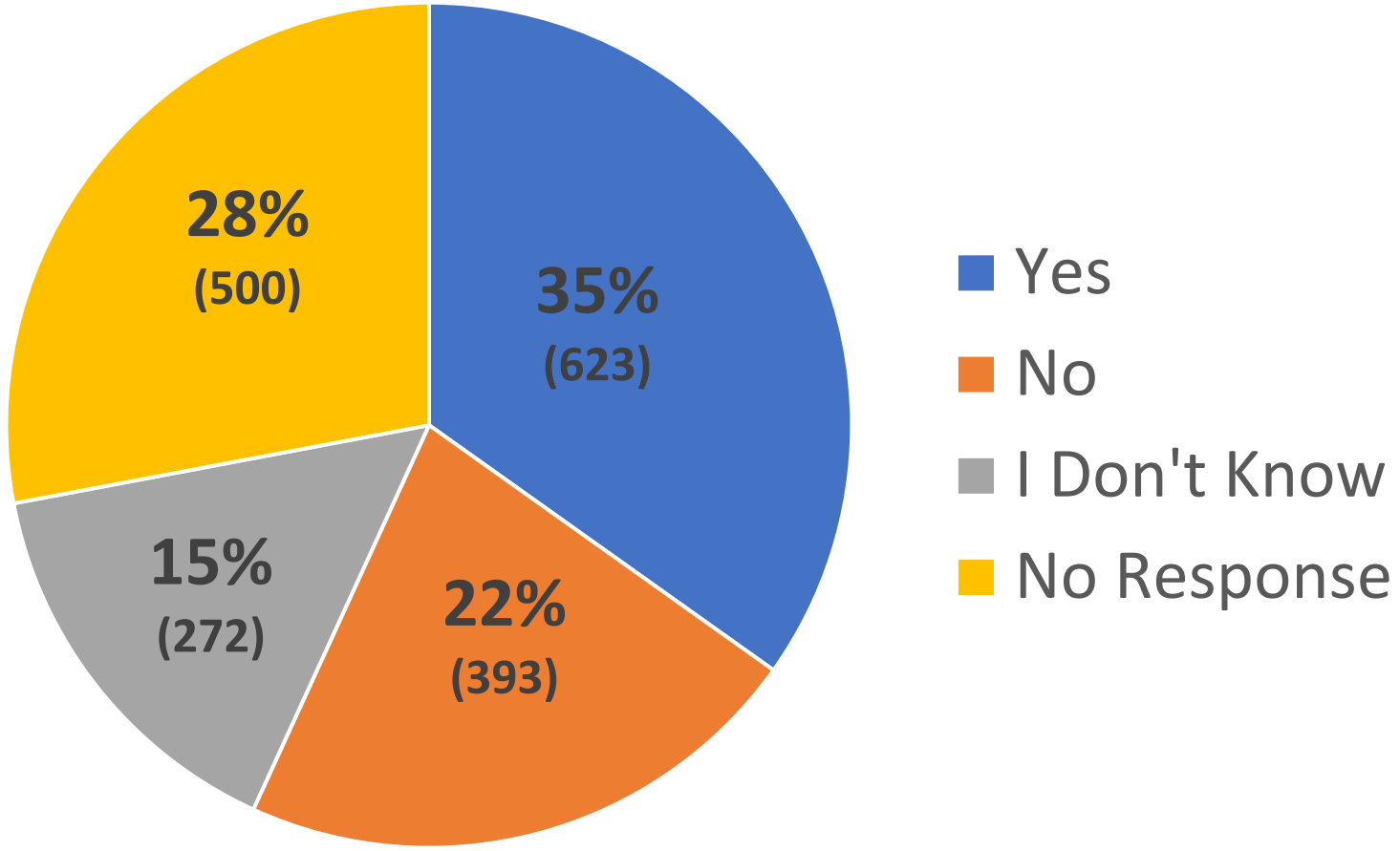
Total Respondents: 1,788

Q5 Do you believe there are additional functions that should be added to a pharmacist's scope of practice?

Common responses

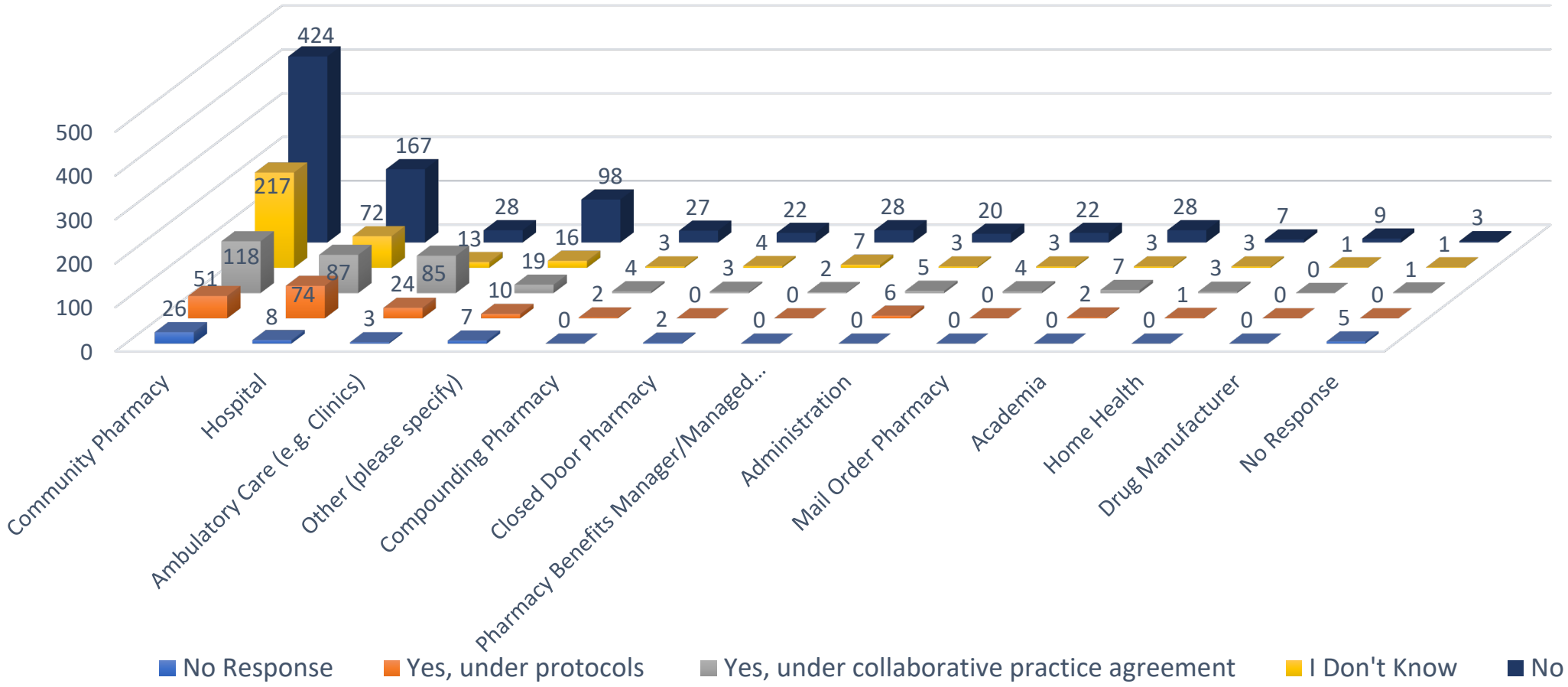
- Dosage change, discontinuation (some indicating under protocol of CPA)
- Ordering Lab
- Prescriptive authority (some indicating under protocol or CPA)
- Vaccinations

Q6 If you answered YES to question 5, do you believe that protocols should be required to perform these additional duties?



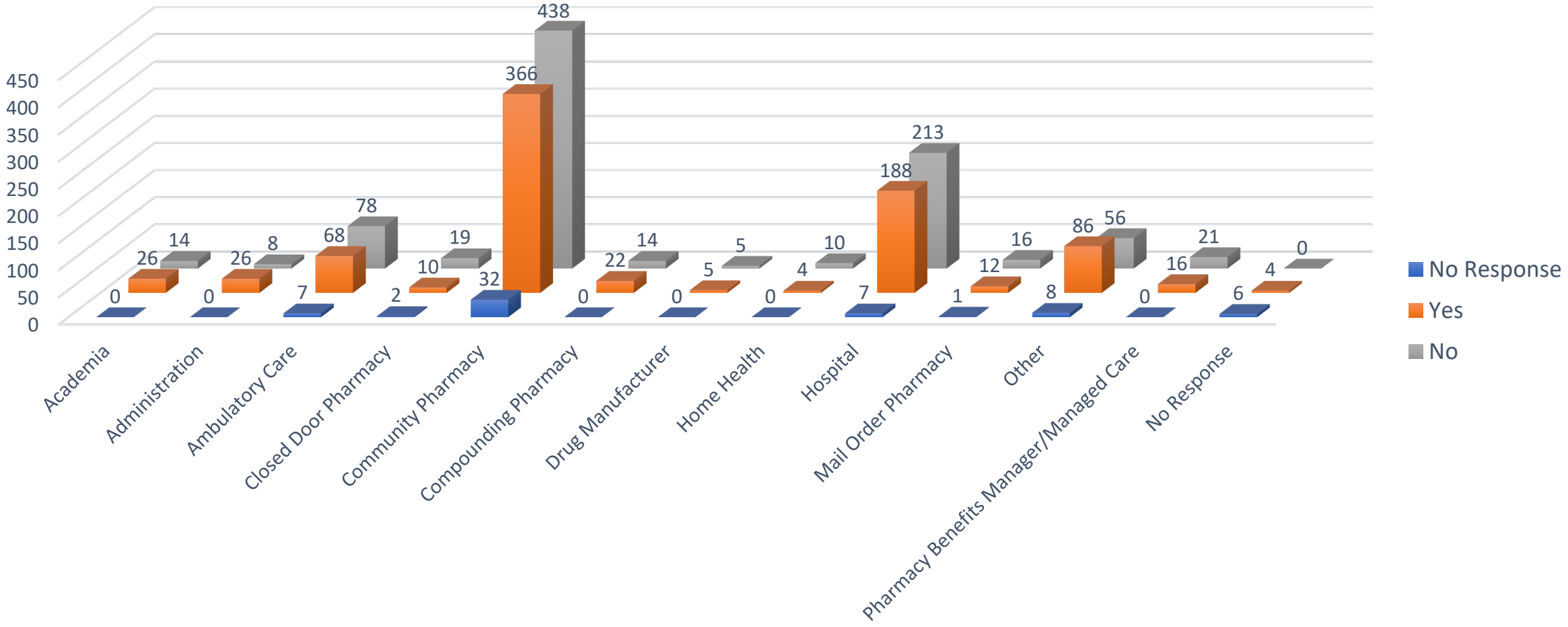
Total Respondents: 1,788

Q7 Do you currently provide patient care services under a collaborative practice agreement or under protocols described in BPC 4052.1 and BPC 4052.2?



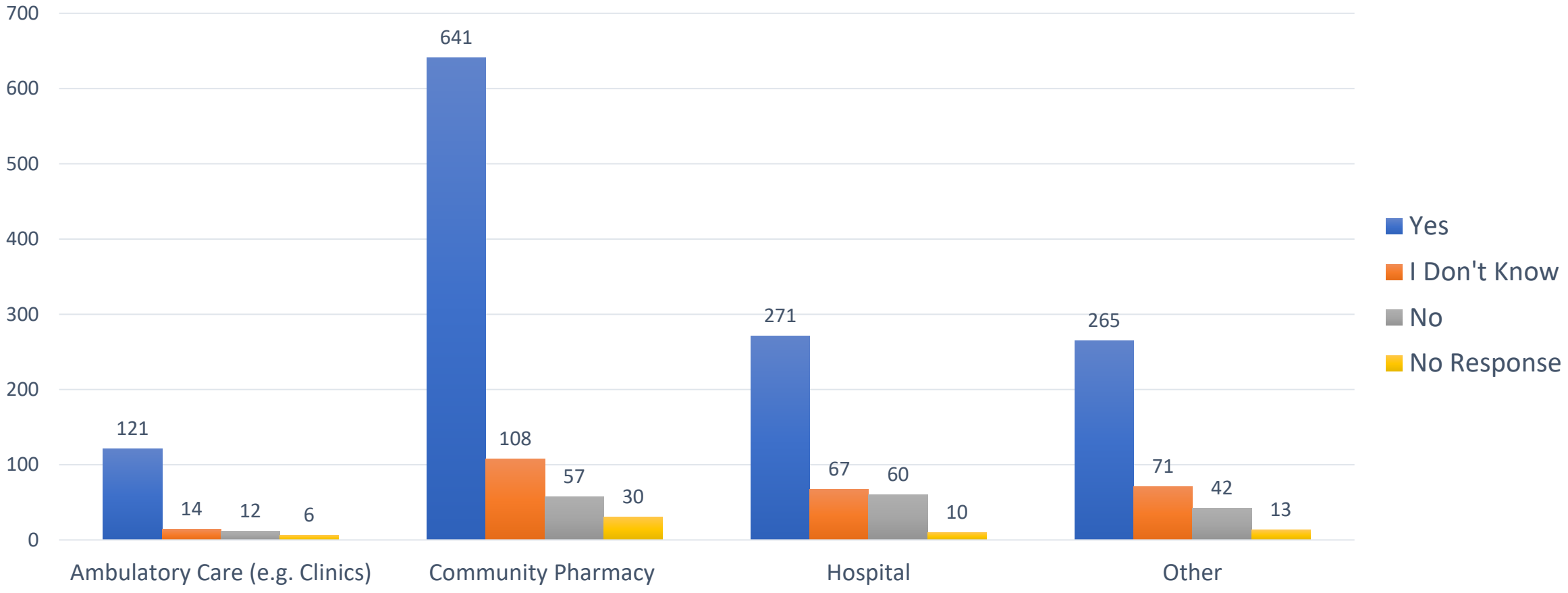
Total Respondents: 1,788

Q8 Are you aware that CA recently enacted legislation that expands collaborative practice agreement authority to all pharmacists to initiate, adjust, or discontinue drug therapy under specified conditions as described in BPC 4052(a)(13)?



Total Respondents: 1,788

Q9 Do you believe there are barriers to providing patient care?



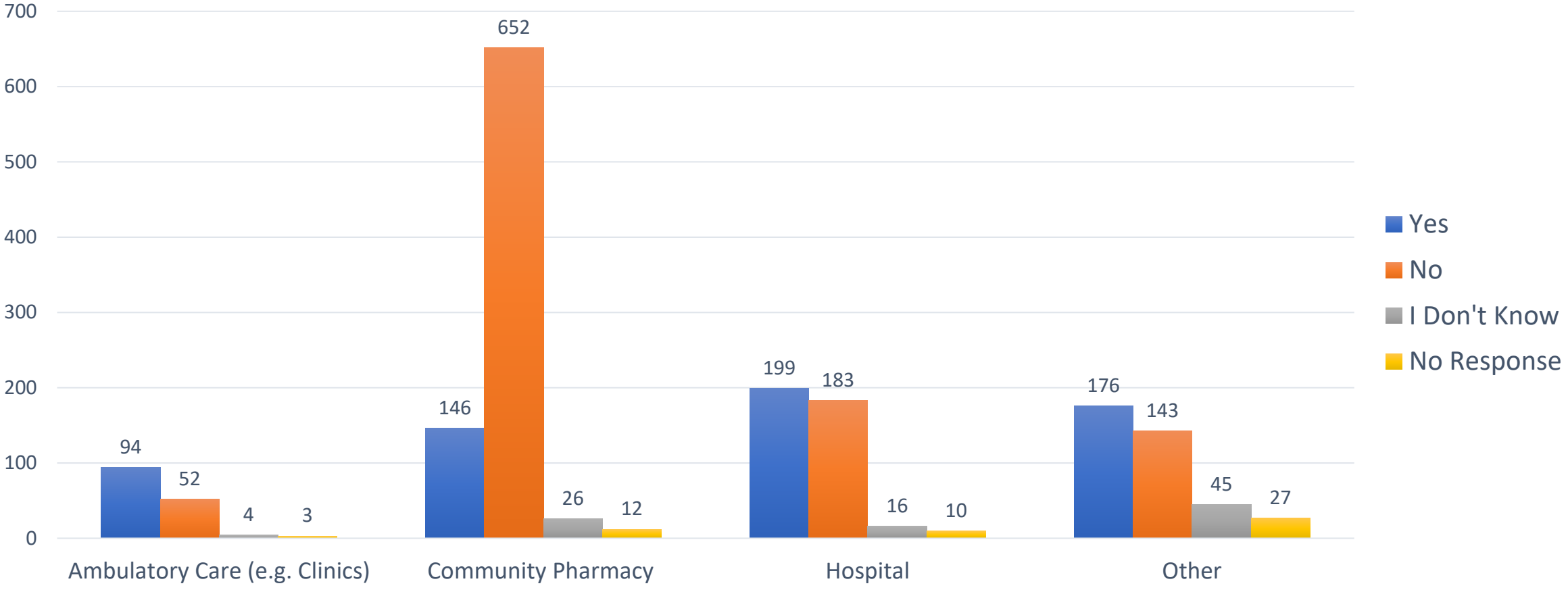
Total Respondents: 1,788

Q9 Do you believe there are barriers to providing patient care?

Common responses

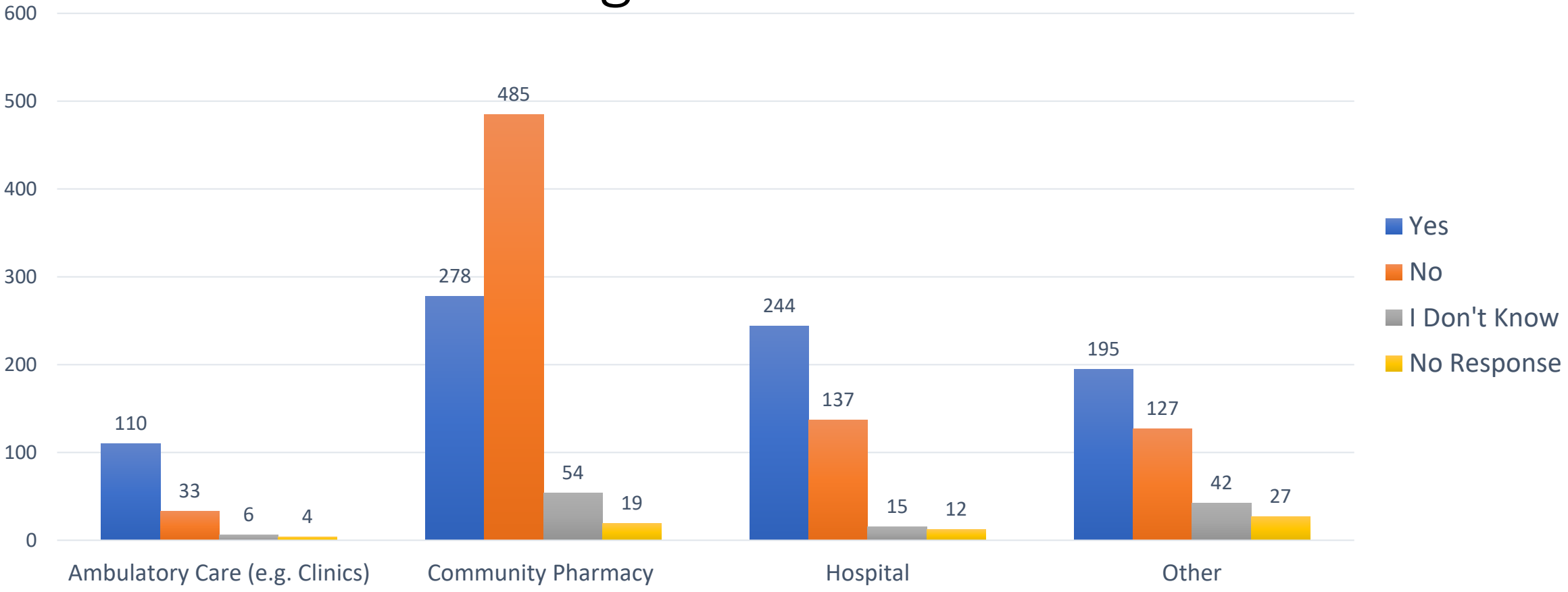
- Lack of access to patient information (Labs, medical records, etc.)
- Insufficient staffing
- Workload and/or metrics
- Inadequate time
- Other HCPs resistance
- Insurance and Reimbursement

Q10 Do you believe that your current work conditions allow sufficient time to make patient-based decisions?



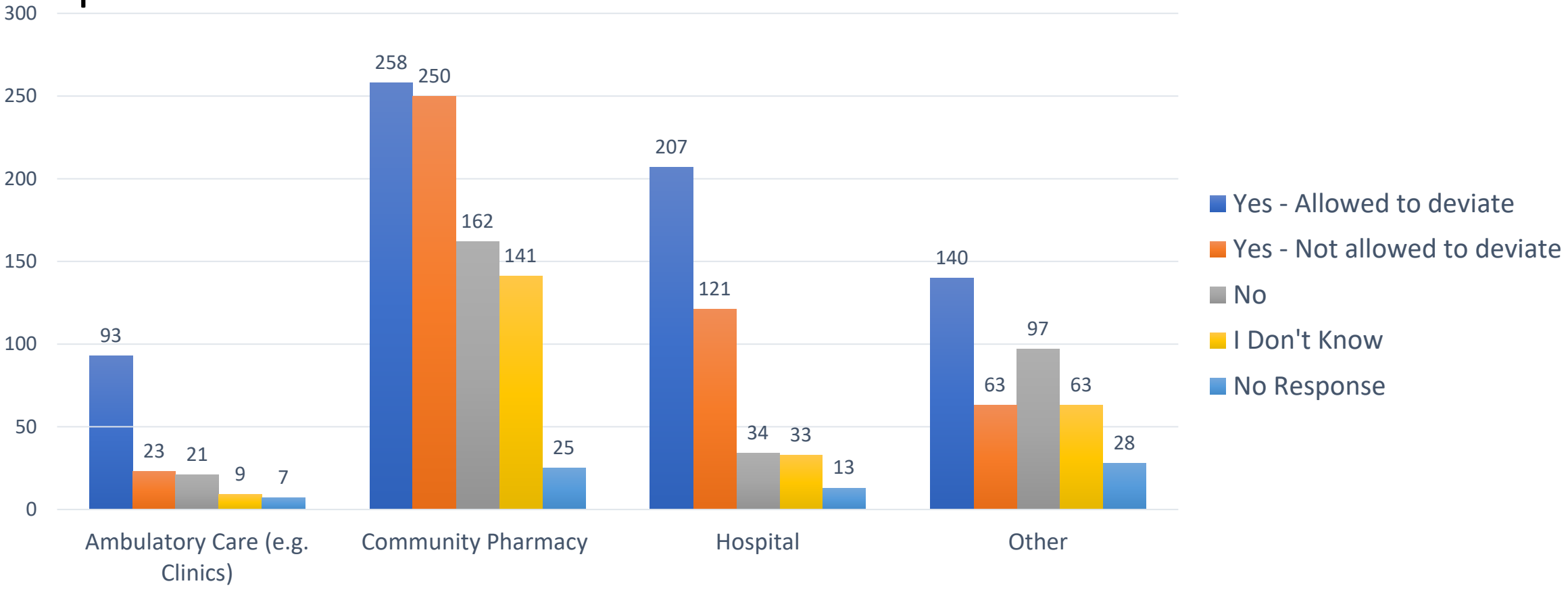
Total Respondents: 1,788

Q11 Do you believe that you have sufficient autonomy to make patient-based decisions in your current work setting?



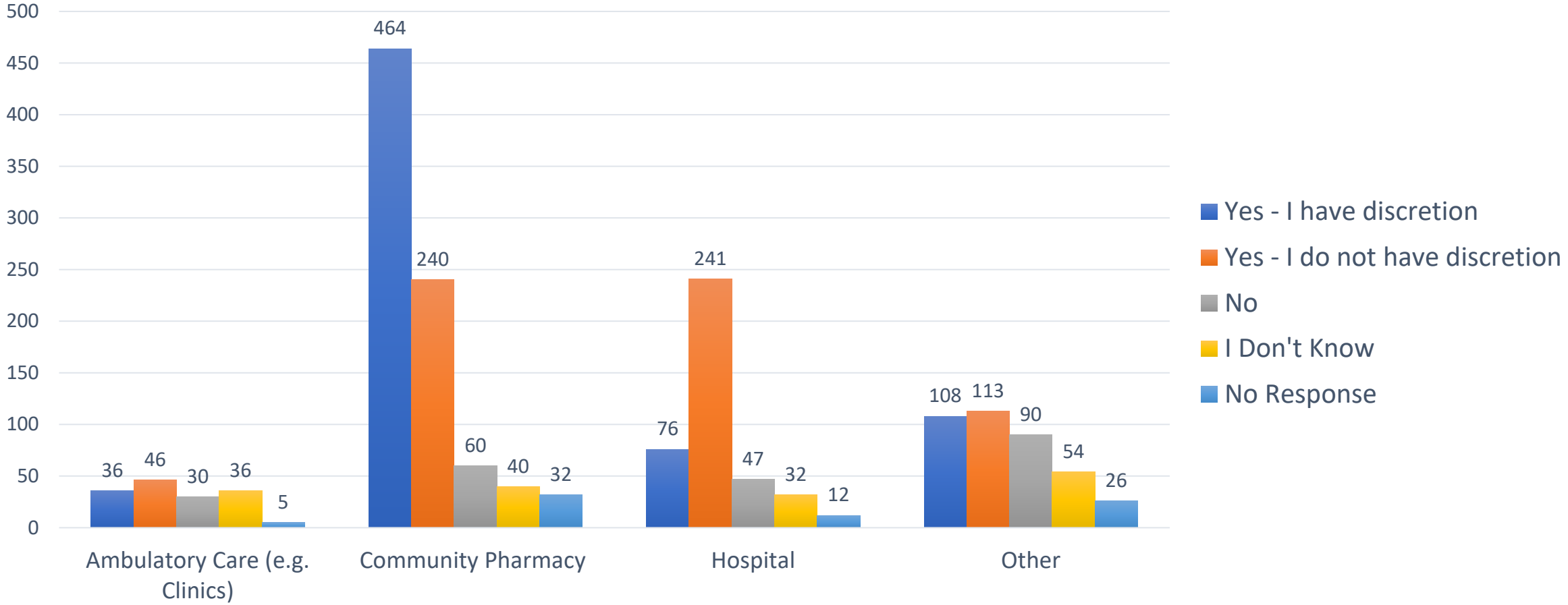
Total Respondents: 1,788

Q12 Does your employer develop policies and procedures that define how you must perform specified functions?



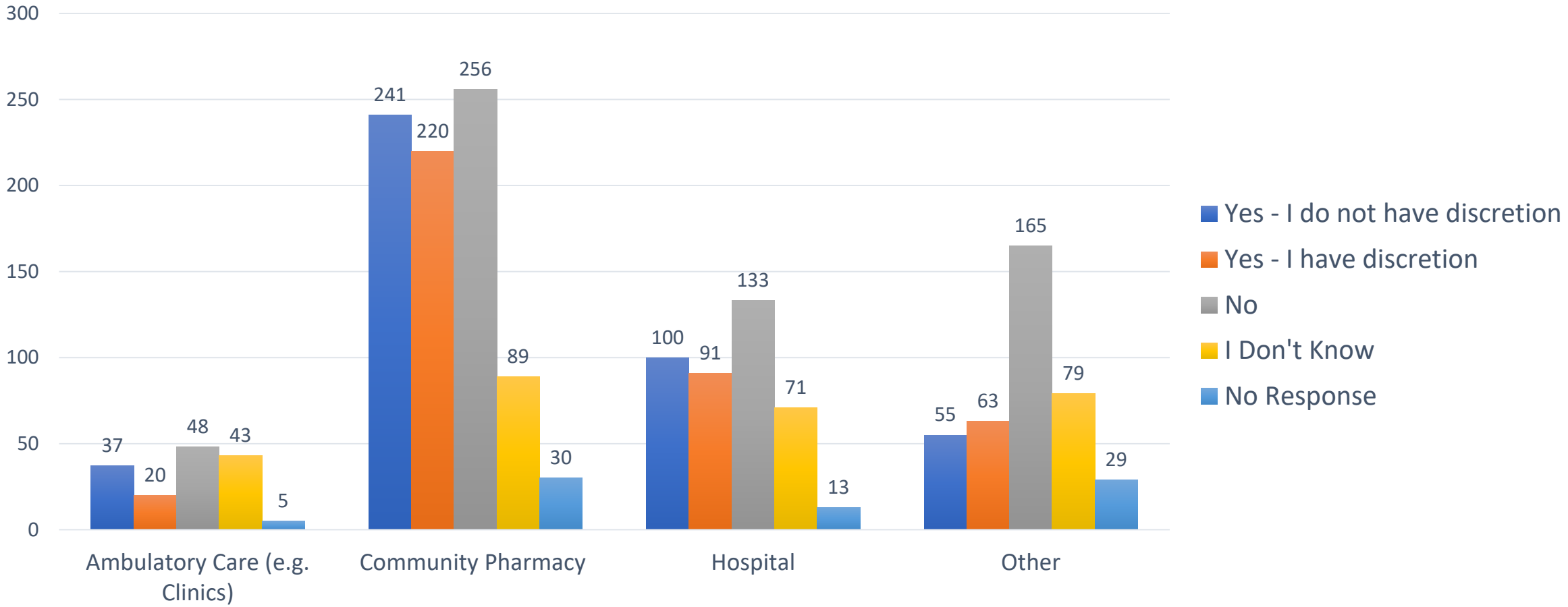
Total Respondents: 1,788

Q13 Has your employer developed policies and procedures related to dispensing of controlled substances?



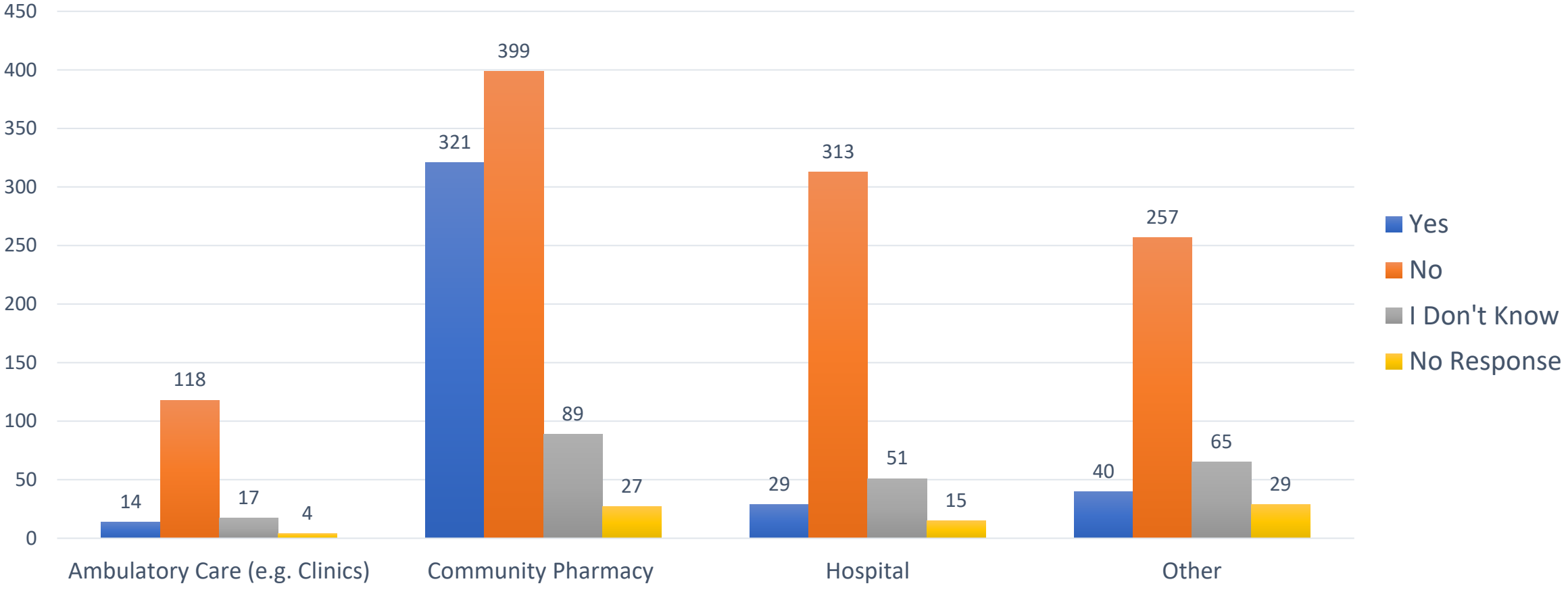
Total Respondents: 1,788

Q14 Has your employer developed a system to block the dispensing of certain types of prescriptions?



Total Respondents: 1,788

Q15 Does your employer have policies and procedures that incentivize performing certain services?



Total Respondents: 1,788