March 2007

Medicare Competitive Acquisition Program (CAP) for Part B Drugs Evaluation

CAP Physician Survey

Office of Management and Budget (OMB) Clearance Package and Data Collection Instrument

Prepared for

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Supporting Statement

Medicare Competitive Acquisition Program (CAP) for Part B Drugs Evaluation

Submitted by:
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A. JUSTIFICATION

A.1 Circumstances of Information Collection

This physician survey is part of an overall evaluation of the Centers for Medicare and Medicaid Services (CMS)'s congressionally mandated Competitive Acquisition for Part B Drugs Program (CAP). MMA § 303(d) requires the implementation of the CAP for those drugs and biologicals covered by Medicare part B that are not paid on a cost or prospective payment system. Since summer 2006 (the original date of January 1, 2006 was delayed), physicians have been given a choice between (1) buying and billing for these covered drugs under the average sales price (ASP) system mandated in § 303(c) of the MMA; or (2) obtaining these drugs from vendors selected for the CAP in a competitive bidding process. If the physician elects to obtain drugs from a CAP vendor, the vendor will bill Medicare for the drug. The CAP is therefore a major change in the way Part B-covered drugs and biologicals are acquired and reimbursed for, requiring CMS to consider many design options. The CAP mandate includes a Report to Congress due July, 1 2008, which will include results from this physician survey.

The CAP has the potential to impact a range of stakeholders, including physicians and other providers, individual beneficiaries, CAP vendors, as well as the CAP designated carriers. Impacts on revenues of physicians are possible (if not likely), as are potential changes in out of pocket costs for beneficiaries. RTI's work to provide technical support for CMS under CAP required that we conduct consultations with physician groups, potential vendors and beneficiary organizations. From that project, we found that physician organizations' pre-implementation feedback on the Congressionally-mandated features of the CAP was not been particularly positive. There was significant concern among oncologists and other specialists that the change to 106 percent of ASP would make it financially impossible for them to continue to administer many Part B drugs to beneficiaries in their offices. They believed that the CAP may not offer an acceptable alternative to acquiring drugs under the 106 percent of ASP system but would remove from physicians the responsibility for collecting beneficiary co-payments.

All interested stakeholder groups with whom we spoke had significant concerns regarding the various operational details of the CAP, but particularly about the ability of the CAP

vendors[1] to deliver necessary drugs to physicians on a timely basis. They were also concerned that vendors may incur significant bad debt, which would jeopardize their participation. If the organizations that apply to be vendors are unaccustomed to levels of bad debt that providers typically incur, they may experience financial difficulty that may cause service to suffer. Or, vendors may be more aggressive with beneficiaries to pay deductibles. As a result, satisfaction with the Medicare program may suffer. Because during this pilot phase of the CAP there is only one vendor, concerns about the single vendor's ability to provide this service may be even more acute. This physician survey will be critical in gathering and comparing physician response to CAP versus the standard Medicare 106 percent of ASP payment system.

A.2 Purposes and Use of Information

Results from this survey will be used by CMS and RTI for the evaluation of the CAP program and for the mandated Report to Congress. In particular, results from this survey will allow CMS and RTI to:

- Determine why physicians chose to (or chose not to) participate in CAP.
- Assess the experience and satisfaction of physicians in the CAP versus the 106 percent of ASP payment methodology..
- Identify specific problems encountered by physicians and their patients under the CAP system.
- Compare the characteristics of physicians in CAP and non-CAP participating practices.

Claims data analysis may not provide a full picture of the impact of CAP participation on physicians and their practices because they cannot inform on the reasoning behind the decisions whether to participate in the program and physicians' satisfaction with the program if they participate. Data from a physician survey will enable analysis of physicians' perceptions on several important indicators. They include perceptions on: (1) how the CAP payment changes have affected their practice; (2) the quality of services provided to beneficiaries, and (3) access to care for these critical drugs. A survey sample of physicians that have and have not elected to participate in CAP will render meaningful comparisons between the perspectives and

1 The language of § 303(d) indicates that at least two CAP vendors be chosen in the competitive bidding. However, since the first implementation of the CAP is considered a pilot program, CMS selected the one bidder considered technically acceptable with an acceptable bid.

characteristics of these two groups of physicians. This detailed feedback will enable CMS to monitor physician satisfaction in CAP relative to ASP reimbursed physicians, looking particularly for changes in physician behavior that might affect beneficiary access to Part B drugs.

A.3 Use of Information Technology

The CAP baseline physician survey will be administered using a mixed mode methodology with the goal to reduce respondent burden. Physician respondents will be offered various options to respond to the survey, including a mail questionnaire and electronic methods for information capturing (i.e., a Web-based questionnaire, computer-assisted telephone interviewing (CATI), and by fax).

For electronic information capturing, we will use a Web-enabled survey system to program the instrument for Web and CATI modes. The survey instrument will be made available at a secure CMS-addressed Web site and is indistinguishable in terms of screen text and skip patterns in these two modes. The only difference among them will be whether the interview is self-administered via the web or interviewer-administered by telephone. The advantages of a web-based instrument include fast and convenient access, on-line help, and real-time data capture.

Respondents will also be offered the option of returning their completed survey by fax through toll-free dedicated lines that will be monitored by authorized staff.

A.4 Efforts to Identify Duplication

This survey gathers physician response to an entirely new program. No other available physician surveys exist that would specifically gather feedback to CAP.

A.5 Involvement of Small Entities

For this evaluation, RTI will conduct a survey with individual physicians who either have or have not elected to participate in the CAP program. Except insofar as individual physicians may be in solo practice or work in small practices, there is no expected involvement for small entities including small businesses, local governments, or other small entities. This project will involve only physicians in either participating practices or the sampled non-participating

practices, which is explained in detail in Section B1 Respondent Universe and Sampling Methods.

A.6 Consequences if Information Collected Less Frequently

This is a one time data collection.

A.7 Special Circumstances

This study will be conducted based on the guidelines put forth in CFR Title 5, Section 1320.5. There will be no special circumstances.

A.8 *Federal Register Notice*/Consultation Outside the Agency

CMS did not receive any comments from the April 20, 2007 60-day Federal Register publication and per OMB no comments were received from the June 29, 2007 30-day Federal Register publication as well.

CMS consulted with several individuals outside the agency to develop the two physician survey instruments. First, experts in health services research, physician payment systems, and survey methodology from RTI International, with whom CMS contracted to conduct this research, designed the data collection instruments with CMS. Then, four physicians (one employee of RTI International and three other physicians) participated in cognitive testing of the data collection instruments and instructions. The cognitive interviews were one-on-one interviews to learn how physicians might interact with the instrument and whether the questions and response options are understandable and complete. This included collecting preliminary information on the length of time needed to complete the data collection. A survey methodologist employed several cognitive interviewing methods, including “think aloud” procedures, retrospective probing techniques, and paraphrasing tasks. For these, respondents were instructed to tell the methodologist what he or she was thinking about in answering a survey question and gave more detailed information about specific aspects of the question or response that affected their comprehension. The results of the cognitive interviews informed revisions to the data collection instruments and instructions. The participants who were not RTI employees were provided a $75 honorarium.

Because this is a one-time data collection, CMS is not intending to engage in future consultation activities related to this data collection.

A.9 Payment to Respondents

The remuneration plan for the CAP baseline survey includes a pre-paid $25 check to physician respondents as a token of appreciation for their cooperation. Literature and our experience both support incentive payments in a pre-paid design as they will provide significant advantages to the study and the government, including:

- Increased responses both from the baseline cohort and the panel cohort in the follow-up
- Reduced data collection costs
- Reduced bias

For a survey of physicians of this kind, gatekeepers in physicians' office may prevent the physicians from knowing about the study, for instance, Parsons (1994) found that as much as 37 percent of refusals in mailed physician surveys came from staff gatekeepers and without any direct physician contact. These gatekeepers may include receptionists, clerks, or medical assistants who usually handle mail, fax, telephone calls, and sometimes e-mails. The pre-paid incentive will help us emphasize the importance of the physicians' participation. Our experience also suggests that to professionals such as physicians, the actual dollar amount is often less important than the gesture made that acknowledges the time and opportunity costs required to complete the survey. Thus, we believe that $25 is a reasonable compensation for respondent burden for a survey of this length.

Further, using incentives can provide cost savings to the government. Literature suggests that pre-paid incentives of even modest amounts may stimulate response and reduce costs associated with follow-throughs (Kellerman & Herold 2001, Berry & Kanouse 1987). The effect is to encourage early questionnaire returns by less expensive modes (mail, fax, or web) and the additional costs of incentives of pre-paid checks (may or may not be cashed by respondents and

non-respondents) are partially offset by a reduction in more expensive telephone reminders or any reminders at all.

Additionally, incentives may counteract resistance among some physician respondents to participate in the follow-up survey (if they are selected to be on the panel). This retention is important in reducing bias because it will ensure that medical specialties with limited representation (e.g., oncologists) in the sample participate at a sufficient rate to maintain the overall representativeness of the panel.

Furthermore, using incentives for a survey of physicians is supported by the final report at the Symposium on Providing Incentives to Survey Respondents (1992) that was sponsored jointly by OMB and the Council of Professional Associations on Federal Statistics. The report recommended that OMB "seriously consider the use of incentives" for surveys:

- Where other organizations routinely pay incentives to the target populations, e.g., doctors.
- When there is a good likelihood a gatekeeper will prevent the respondent from ever receiving the questionnaire.
- That are part of longitudinal panels.

In sum, we believe that our remuneration plan is a cost effective way to collect data for the CAP baseline survey as it will also ensure the collection of useful, cost effective, and policy relevant data for the CAP evaluation.

A.10 Assurance of Confidentiality

A plan for assuring the confidentiality of the project includes signing ethics agreements from all personnel employed by the contractor who will have access to individual identifiers. Also included in the plan is personnel training regarding the significance and protection of confidentiality, particularly as it relates to controlled and protected access to computer files under the control of a single database manager; built-in safeguards concerning status monitoring and receipt control systems; a secured and operator-manned in-house computing facility; and handling requests for information and providing assurance to respondents about the protection of their responses.

Further, materials will be sent to sample members describing the purpose and the voluntary nature of this survey, as well as conveying the extent to which respondents and their responses will be kept confidential. The materials include an advance letter, a letter accompanying the survey, follow-up letters (if necessary), and a Frequently Asked Questions.

Task 8 of RTI's contract requires that all electronic files containing the survey data be delivered to CMS at the end of the contract. To preserve respondents' confidentiality, neither names nor addresses will be included on any data file. A study identification number will be assigned to each respondent, and a separate locator database, containing the Unique Physician Identification Number (UPIN) for these sample members will be maintained in a secure location. All hard-copy tracing directory updates will be destroyed after they are entered into magnetic form and verified.

A.11 Questions of a Sensitive Nature

Information collected in this survey is not of a sensitive nature. Questions are confined to physician opinions and perspectives, as well as collection of some basic demographic and practice information. Physicians are a difficult population to recruit into surveys and it is important to minimize the response burden by developing a succinct questionnaire that focuses on those issues required for the assessment. Therefore, in the physician survey, we are especially interested in the perceptions of physicians regarding the Medicare Part B payment changes.

A.12 Estimates of Hour Burden

Two versions of the survey will be fielded in the baseline survey data collection: (1) CAP Participating Physician Survey and (2) CAP Non-Participating Physician Survey. Physicians who have elected to participate in the CAP program will receive the version for the participating physicians, and physicians who have not elected to participate in the CAP program will receive the version for the non-participating physicians.

The average length of the participating physician version is 15 minutes, including time to examine the entire mail package. In contrast, the non-participating physician version averages 8 minutes in length.

The respondent burden for the CAP baseline survey is shown in ***Exhibit 1***.

Exhibit 1. Respondent Burden

Form Name	Number of Respondents	Responses Per Respondent	Hours per Respondent	Total Burden (hours)
CAP Participating (Demonstration)	780	1	0.25	195.0
CAP Non-Participating (Comparison)	780	1	0.13	101.4
TOTAL	1,560			296.5

A.13 Estimates of Cost Burden to Respondents

There are neither capital or startup costs nor are there any operation and maintenance costs to respondents.

A.14 Estimates of Annualized Cost Burden to the Government

Total costs associated with the CAP baseline survey are estimated to be $325,840 for sampling, data collection, processing, and analysis over a 12 month period of performance. The annualized cost is approximately $325,840.

A.15 Changes in Burden

This is a new data collection for the Center of Medicare and Medicaid Services (CMS).

A.16 Time Schedule, Publication, and Analysis Plans

The primary purpose for this survey is to add to the analyses included in a mandated Report to Congress. No other publication is anticipated at this time. The mandated Report to Congress is due July 2008, though a delay in the original start date of the CAP implementation will make the inclusion of a full evaluation of the CAP impossible at that time. This will not delay the Report to Congress. CMS will submit further analyses pertaining to the CAP when it is available. CMS intends to include the results from this survey in the Report to Congress.

A.17 Display of Expiration Dates

The OMB expiration date will be displayed on all disseminated data collection materials.

A.18 Exceptions to Certification Statement

There are no exceptions to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

The study is focused on obtaining survey estimates from two populations: (1) physicians that have elected to participate in CAP and (2) physicians that have not. The CAP-participating group is much smaller than its counterpart. There are 2,199 CAP physicians in 680 practices, as compared to greater magnitudes of non-CAP physicians and practices (exact numbers are unknown at this time). We are anticipating a response rate of approximately 65%.

Using the December 31, 2006 update of the CAP election database provided by Noridian Administrative Services (the CAP Designated Carrier), ***Exhibit 2*** shows that solo practitioners compose nearly half of the CAP practices participating in 2007. While 90 percent of the CAP practices have ten or fewer physicians, the remaining ten percent includes large practices. The top four largest practices have 118, 126, 128, and 205 physicians and represent 26 percent of this population. The respondent population is discussed in greater details in Section B2.

Exhibit 2. Size of CAP-Participating Practices

Practice Size	Frequency	Percentage	Cumulative Percentage
1	331	48.68%	48.68%
2–5	216	31.76	80.44
6–10	64	9.41	89.85
11–25	41	6.03	95.88
26–50	20	2.94	98.82
51–100	4	0.59	99.41
101+	4	0.59	100.00

B.2 Information Collection Procedures

The sample size for this survey will be 2,400 physicians, consisting of 1,200 physicians from the CAP-participating group and 1,200 from the CAP non-participating groups. We intend on sampling at least one physician from each practice for two reasons: (1) examining how CAP has impacted physician practices; and (2) there may be some degree of homogeneity within a practice.

As mentioned in Section B1, there are 680 CAP-participating practices in 2007, and one physician will be sampled from each practice. The remaining 520 CAP physicians (1200 – 680 = 520) will be optimally allocated (to minimize variances of estimates from analysis of the survey data) based on the size of the practice. This means that larger practices will tend to have a larger share of the remaining sample. The sample from the non-CAP physicians will mirror the CAP group in terms of cell sizes. We intend to sample from 680 non-CAP practices and the remaining sample will be proportionally allocated. However, this is not a case-control design where we would try to pair a CAP practice with a non-CAP practice based on certain characteristic. We do not feel there is sufficient data for case-control matching.

A sample design of this kind allows us to examine the data in two different ways. First, we have representation from every CAP practice. All of the small practices with one or two physicians will have a voice in the study if they choose to participate. Second, given that the design is quasi-proportional, we can re-weight the data based on practice size and obtain estimates about the CAP program as a whole with modest design effects.

A recent survey of primary care physicians regarding cancer screening knowledge, conducted by researchers for the National Cancer Institute realized a 72 percent response rate (1,718 physicians) using a mixed-mode survey instrument.[2] That study used a $50 honorarium, rather than the $25 for this survey, and the questions related to knowledge and awareness of clinical topics, which physicians may be more interested in responding to than questions about a Medicare program. In light of these considerations, we are assuming a somewhat lower response rate of 65 percent. This estimate incorporates both non-response to the entire survey as well as item non-response for key items requiring knowledge of the practice's decision to participate as well as on effects on their patients.

Assuming a 65 percent response rate, each group will result in 780 respondents. Considering item non-response and design effects, an effective sample size of 400 or more respondents can be expected for any given survey item. With an effective sample size of 400 respondents, we will be able to construct 95 percent confidence intervals with five percent error bounds even where variances of estimates of proportions are highest (at 50 percent responding in each category). This is also an ideal size for making comparisons between the CAP and non-

2 An electronic copy of this study is available at < http://healthservices.cancer.gov/surveys/colorectal/pcpoverview0303.pdf>.

CAP physicians. Approximately eighty percent power will be rendered to detect at least ten percent differences between the two groups with 95 percent confidence levels. The survey analyses will primarily consist of analyses of proportions (e.g., proportion of physicians responding that they were somewhat or very satisfied with the customer service of the CAP vendor). The reasons are two-fold. First, most of the survey questions are ordered, qualitative measures of satisfaction, which are naturally analyzed as the proportion of physicians who responded that they were at least somewhat satisfied or were very satisfied. The questions that are not ordered satisfaction questions are multinomial in nature, thus proportions responding in each category are the natural method of analysis.

Furthermore, consideration was given to stratifying on physician specialty, particularly oncology and rheumatology. Because of the small number (less than 50) of these CAP-participating specialists, we chose to focus strictly on the practices. Covariates will likely be included in our analytic models to denote physician specialty, but we will not be making specific estimates.

We do not intend to impute missing data. A certain level of item non-response has been assumed within the survey and incorporated into our sample size estimates. As noted above, we expect that some physicians may not know why their practice decided to participate in the program (and may not care to take the time to find out), and they may not feel comfortable reporting on how they feel the program has affected their patients (they may feel they do not have sufficient knowledge). However, we do intend to make an adjustment for overall non-response to the survey as a whole. After the initial design based weights (inverse of the probabilities of selection) have been constructed, we will then make a weight class adjustment so that the sums represent respondents and non-respondents. We anticipate that our weight classes will be CAP-participating/non-participating, practice size, and the state location of the practice. All analyses of the survey responses will be performed using these weights so that the respondents can represent themselves and the non-respondents and to correct for intentional over- or under-sampling of certain physicians to optimally reduce estimate variances. This should address some of the concern of response bias due to the lower response rate, assuming that the responses are not discordant to the non-respondent population (had they been obtained). All analyses will be performed using SAS v9.1.3 (Service Pack 2).

Operationally, a mixed mode methodology will be implemented with the following design:

- A mail questionnaire that can be read by optical-scanning technology
- A Web-based questionnaire available at a secure CMS-addressed Web site
- Computer-assisted telephone interviewing (CATI) allowing for both outbound calls and dedicated toll free-inbound service
- By fax through toll-free dedicated lines

Preceded by an advance letter, we will employ a four-wave mailing to physicians in the sample and final prompting by computer-assisted telephone interviewing (CATI) staff.

Mail supervisors, data entry coders, as well as CATI interviewers will undergo a minimum of 8 hours training, which will cover complete editing and processing instructions for data handling. Before each wave of mailing, supervisors will randomly check a sample of packages for completeness and replace damaged materials. Supervisors will also ensure that each wave goes out on schedule. Upon receipt of completed questionnaires, we will use a verification procedure to compute and monitor quality control and data entry coders will code the responses right away. In the final stage of data collection, CATI interviewers will prompt respondents who have not returned a completed questionnaire. The interviewers will be monitored and evaluated using listening devices, and their performance is reviewed each week. An automatic call distributor system will be used to create a daily record of telephone calls processed, which helps monitor project costs and progress. Once data are collected either by mail, telephone, or fax, further contact attempts will stop.

B.3 Methods to Maximize Response Rates

To achieve the highest possible response rates of physician respondents, we will employ a sophisticated design that is modeled on the tailored design method (Dillman 2000). Our methods include:

- **Mixed-Mode Methodology.** Literature has shown that among certain physicians, mail is a preferred method of survey participation, as evidenced by higher response rates than other modes. However, a significant number of physicians – who would not otherwise participate in a survey – will respond only by the Web (Olson et al. 1999;

Shosteck and Fairweather 1979). We will offer the survey in both mail and Web form, with and an additional telephone prompting. Respondents will also have the option of faxing a completed survey via dedicated toll-free lines.

- **Four Contacts by Mail Preceded by an Advance Letter, with an Additional Special Contact.** We will deploy a four-wave mailing with a special contact:
  - **Advance Letter.** Using First Class mail, a lead letter will be mailed to inform the physician that he or she had been selected to participate and introduce him or her to the need for their participating in this data collection effort.
  - **First Contact.** Using First Class mail, a cover letter, Frequently Asked Questions (FAQ) information, and a copy of the questionnaire will be mailed within a week of the advance mailing.
  - **Second Contact.** After three weeks have elapsed since the first contact, respondents who have not returned a completed survey by mail, Web, or fax will be sent a reminder and thank you post card.
  - **Third and Fourth Contacts.** Alternating between First Class mail and FedEx delivery, Third and Fourth Contacts would also carry a cover letter and a copy of the questionnaire and will be mailed after sufficient time has passed since the previous wave.
  - **Special Contact (Final CATI Prompting).** At the final stage of data collection, non-respondents will be prompted by telephone by CATI interviewers.

- • **Physician Respondent-Friendly Questionnaire.** We have learned from experience and literature that physician respondents are reluctant to participate in survey research when they find that an instrument is lengthy, forces them to over-generalize, or when the instruments “don’t make sense” (Jepson et al. 2005). We have kept the questionnaire to no more than 5 pages of text for the participating physician survey and 1 page for the non-participating physician survey. Based on the result of a pretest, we also improved the questionnaire to only include the most relevant questions and in straightforward language.

- **Proven Strategies to Raise Legitimacy of the Study.** We will apply several proven strategies documented in the literature (Del Valle et al. 1997, Tambor et al. 1993, Oden and Price 1999).
    - **Attractive Packaging.** The mail package will use different size envelopes and individual stamps rather than metered mail. Mailings at the third and fourth contacts will alternate between US Postal Service (First Class mail) and FedEx delivery.
    - **Endorsements.** Cover letters will use CMS stationery and shall be accompanied by an endorsement letter once we obtain the endorsements from appropriate medical societies.
    - **Return Envelopes.** A return envelope (stamped or business-reply) will be made available in each mail package.
    - **Token Prepaid Financial Incentive.** A check in the amount of $25 will be offered in a prepaid fashion in the First Contact mailing to emphasize the importance of respondents' participation. It also demonstrates our appreciation for their efforts. As reported earlier, our experience suggests that to professionals such as physicians, the actual dollar amount is often less important than the gesture made that acknowledges the time and opportunity costs required to complete the survey.

- **Personalized Lead Letter and Correspondence.** We will personalize salutations in all respondent correspondences. Specifically, a customized lead letter will be sent in advance of fielding to promote respondent cooperation. This lead letter will explain the study objectives, emphasize that the survey is voluntary, and assure confidentiality. Moreover, the letter will provide several means for respondents to contact us, including a toll-free telephone number and E-mail address.

B.4 Test of Procedures

Using RTI's Questionnaire Appraisal System (QAS), we conducted a structured and standardized instrument review in evaluating question features that are likely to lead to response

error. The QAS review was the first step in the pre-testing effort as it focused on question wording, placement, and flow within the questionnaire.

To complete the pretest, we conducted four tests of the questionnaire. Physician respondents were recruited from medical specialties that would participate in the CAP program so that they resembled our expected survey respondents as much as possible. To replicate the planned data collection mode, they were mailed a questionnaire. These pretest respondents later completed a retrospective debriefing over the telephone about how they interacted with the instrument, the length of time spent, and how they understood the survey questions.

The pretest pointed to the need for three improvements in the questionnaire. First, several phrases, response options, and items were reworded to address confusion expressed by the respondents. Second, transitional statements and instructions were added to aid the respondents in navigating the questionnaire. Finally, the questionnaire formatting was modified to reduce length and enhance its attractiveness. The final version of the questionnaire that will be used for the CAP survey is included in Appendices G and H.

B.5 Statistical Consultants

The survey will be conducted and analyzed by staff at RTI, International. The RTI project director is Dr. Edward M. Drozd. The RTI statistician on this project is Dr. Scott Scheffler.

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ATTACHMENT A

60-DAY FEDERAL REGISTER NOTICE

(To be added after issue by CMS)

ATTACHMENT B

30-DAY FEDERAL REGISTER NOTICE

(To be added after issue by CMS)

ATTACHMENT C

ADVANCE LETTER

CMS Letterhead

Dear Dr. [FIRST NAME] [LAST NAME]:

I am writing to ask for your help with an important study about your practice's participation in the Medicare Competitive Acquisition Program for Part B Drugs and Biologicals (CAP).

The agency that oversees Medicare, the Centers for Medicare & Medicaid Services (CMS) has asked RTI International, a not-for-profit research organization, to administer a survey for this study. **CMS wants to understand why physician practices decided to participate in this program as well as their satisfaction with it**. The purpose of this survey is to gather physician feedback on their satisfaction with this program so that CMS can take physicians' views into consideration when monitoring this program and evaluating potential changes to it**.**

In a few days, you will receive a survey questionnaire that will take no longer than 15 minutes to complete. A Web version of the survey will also be available.

Please be assured that all information you provide in the survey will be kept strictly confidential. We are required by federal law to protect this information. Neither you nor your practice will be identified by name in the reports from this study. If you have questions related to your rights as a survey respondent, you may call RTI's Office of Research Protections toll-free at 1-866-214-2043. If you have questions about this study, please contact us toll-free at 1-XXX-XXX-XXXX or by e-mail at XXXX@rti.org.

Your help is extremely important to the success of the Medicare program and CMS, and we thank you in advance for your cooperation.

Sincerely,

Edward M. Drozd
RTI Project Director

What is the CAP? The Medicare program traditionally pays for some drugs and biologicals prescribed by physicians on behalf of their Medicare patients and generally administered by physicians. These drugs and biologicals are covered under the Medicare Part B program, and are *different* from prescription drugs newly covered under the Medicare prescription drug plans (Part D). CMS has recently implemented some Congressionally-mandated changes to the way these Medicare Part B covered drugs are reimbursed. There are currently two options for acquiring these drugs and biologicals that physicians can elect: (1) reimbursement based on 106 percent of Average Sales Price (ASP), or (2) acquiring drugs and biologicals from the Medicare-approved vendor under the Competitive Acquisition Program for Part B Drugs and Biologicals (CAP).

CMS Letterhead

Dear Dr. [FIRST NAME] [LAST NAME]:

I am writing to ask for your help with an important study about the Medicare Competitive Acquisition Program for Part B Drugs and Biologicals (CAP). The agency that oversees Medicare, the Centers for Medicare & Medicaid Services (CMS) has asked RTI International, a not-for-profit research organization, to administer a survey for this study.

Your practice has elected *not* to participate in the CAP program, and CMS would like to understand why your practice decided not to participate in this program. The purpose of this survey is to gather physician feedback so that CMS can take physicians' views into consideration when monitoring this program and evaluating potential changes to it .

In a few days, you will receive a survey questionnaire that will take no longer than 8 minutes to complete. A Web version of the survey will also be available.

Please be assured that all information you provide in the survey will be kept strictly confidential. We are required by federal law to protect this information. Neither you nor your practice will be identified by name in the reports from this study. If you have questions related to your rights as a survey respondent, you may call RTI's Office of Research Protections toll-free at 1-866-214-2043. If you have questions about this study, please contact us toll-free at 1-XXX-XXX-XXXX or by e-mail at XXXX@rti.org.

Your help is extremely important to the success of the Medicare program and CMS, and we thank you in advance for your cooperation.

Sincerely,

Edward M. Drozd
RTI Project Director

What is the CAP? The Medicare program traditionally pays for some drugs and biologicals prescribed by physicians on behalf of their Medicare patients and generally administered by physicians. These drugs and biologicals are covered under the Medicare Part B program, and are *different* from prescription drugs newly covered under the Medicare prescription drug plans (Part D). CMS has recently implemented some Congressionally-mandated changes to the way these Medicare Part B covered drugs are reimbursed. There are currently two options for acquiring these drugs and biologicals that physicians can elect: (1) reimbursement based on 106 percent of Average Sales Price (ASP), or (2) acquiring drugs and biologicals from the Medicare-approved vendor under the Competitive Acquisition Program for Part B Drugs and Biologicals (CAP).

ATTACHMENT D

COVER LETTER ACCOMPANYING SURVEY

CMS Letterhead

Dear Dr. [FIRST NAME] [LAST NAME]:

This survey has been sent to you because this practice has elected to participate in the Medicare Competitive Acquisition Program for Part B Drugs and Biologicals (CAP) offered by the Center for Medicare & Medicaid Services (CMS). We ask that you complete the survey in the next few weeks so that the CMS can use this information to improve the CAP program.

We have enclosed a $25 check to demonstrate the importance of your informing us on your satisfaction with the CAP program. It is yours to keep even if you decide not to complete the survey. However, we hope you will be willing to help the CMS so that they can take physicians' views into consideration when implementing competitive bidding for Medicare programs.

There are three convenient ways to complete the survey:

1) Complete the **enclosed survey** and return in the return envelope or by fax to XXX-XXX-XXXX.
2) Go to www.XXXXX.gov to complete an **on-line survey**
3) Call us toll-free at 1-XXX-XXX-XXXX to complete the survey **by telephone**

It will take no longer than 15 minutes to complete the survey and reading this letter and enclosed materials. CMS has asked RTI International, a non-for-profit research organization, to administer this survey. Please be assured that all information you provide will be kept strictly confidential. We are required by federal law to protect this information. Neither you nor your practice will be identified by name in the reports from this study. If you have questions or concerns about this study, please contact us toll-free at 1-XXX-XXX-XXXX or by e-mail at XXXX@rti.org.

Your help is extremely important to the success of the Medicare program and CMS, and we thank you in advance for your cooperation.

Sincerely,

Edward M. Drozd
RTI Project Director

What is the CAP? The Medicare program traditionally pays for some drugs and biologicals prescribed by physicians on behalf of their Medicare patients and generally administered by physicians. These drugs and biologicals are covered under the Medicare Part B program, and are *different* from prescription drugs newly covered under the Medicare prescription drug plans (Part D). CMS has recently implemented some Congressionally-mandated changes to the way these Medicare Part B covered drugs are reimbursed. There are currently two options for acquiring these drugs and biologicals that physicians can elect: (1) reimbursement based on 106 percent of Average Sales Price (ASP), or (2) acquiring drugs and biologicals from the Medicare-approved vendor under the Competitive Acquisition Program for Part B Drugs and Biologicals (CAP).

CMS Letterhead

Dear Dr. [FIRST NAME] [LAST NAME]:

This survey has been sent to you because this practice has elected *not* to participate in the Medicare Competitive Acquisition Program for Part B Drugs and Biologicals (CAP) offered by the Center for Medicare & Medicaid Services (CMS). We ask that you complete the survey in the next few weeks so that the CMS can understand why you decided not to participate in the CAP program.

We have enclosed a $25 check to demonstrate the importance of your informing us about the CAP program. It is yours to keep even if you decide not to complete the survey. However, we hope you will be willing to help the CMS so that they can take physicians' views into consideration when implementing competitive bidding for Medicare programs.

There are three convenient ways to complete the survey:

1) Complete the **enclosed survey** and return in the return envelope or by fax to XXX-XXX-XXXX.
2) Go to www.XXXXX.gov to complete an **on-line survey**
3) Call us toll-free at 1-XXX-XXX-XXXX to complete the survey **by telephone**

It will take no longer than 8 minutes to complete the survey and reading this letter and enclosed materials. CMS has asked RTI International, a non-for-profit research organization, to administer this survey. Please be assured that all information you provide will be kept strictly confidential. We are required by federal law to protect this information. Neither you nor your practice will be identified by name in the reports from this study. If you have questions or concerns about this study, please contact us toll-free at 1-XXX-XXX-XXXX or by e-mail at XXXX@rti.org.

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ATTACHMENT E

FOLLOW-UP LETTER ACCOMPANYING SURVEY

CMS Letterhead

Dear Dr. [FIRST NAME] [LAST NAME]:

We really need your help! My name is Edward Drozd, the Project Director for the CAP study conducted for the Center for Medicare & Medicaid Services (CMS) and I would like to make a personal appeal to you.

I know how busy you must be with your own work and family matters. But we are asking for your help to complete this survey because your practice has elected to participate in the Medicare Competitive Acquisition Program for Part B Drugs and Biologicals (CAP). We need information from CAP participating physicians like yourself so that CMS may understand why physicians decide to participate in the CAP program and their satisfaction with it. CMS would like to take your views into consideration in order to improve the CAP program.

It will take no longer than 15 minutes to complete the survey and reading this letter. There are three convenient ways to complete the survey:

1) Complete the **enclosed survey** and return in the return envelope or by fax to XXX-XXX-XXXX.
2) Go to www.XXXXX.gov to complete an **on-line survey**
3) Call us toll-free at 1-XXX-XXX-XXXX to complete the survey **by telephone**

We are required by federal law to protect your identity and the information that you provide. If you have questions or concerns, please contact us toll-free at 1-XXX-XXX-XXXX or by e-mail at XXXX@rti.org.

Please accept my deepest thanks and appreciation for any help you may provide.

Sincerely,

Edward M. Drozd
RTI Project Director

What is the CAP? The Medicare program traditionally pays for some drugs and biologicals prescribed by physicians on behalf of their Medicare patients and generally administered by physicians. These drugs and biologicals are covered under the Medicare Part B program, and are *different* from prescription drugs newly covered under the Medicare prescription drug plans (Part D). CMS has recently implemented some Congressionally-mandated changes to the way these Medicare Part B covered drugs are reimbursed. There are currently two options for acquiring these drugs and biologicals that physicians can elect: (1) reimbursement based on 106 percent of Average Sales Price (ASP), or (2) acquiring drugs and biologicals from the Medicare-approved vendor under the Competitive Acquisition Program for Part B Drugs and Biologicals (CAP).

CMS Letterhead

Dear Dr. [FIRST NAME] [LAST NAME]:

We really need your help! My name is Edward Drozd, the Project Director for the CAP study conducted for the Center for Medicare & Medicaid Services (CMS) and I would like to make a personal appeal to you.

I know how busy you must be with your own work and family matters. But we are asking for your help to complete this survey because your practice has *not* elected to participate in the Medicare Competitive Acquisition Program for Part B Drugs and Biologicals (CAP). We need information from physicians like yourself so that CMS may understand why physicians make their decisions not to participate. CMS would like to take your views into consideration.

It will take no longer than 8 minutes to complete the survey and reading this letter. There are three convenient ways to complete the survey:

1) Complete the **enclosed survey** and return in the return envelope or by fax to XXX-XXX-XXXX.
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Sincerely,

Edward M. Drozd
RTI Project Director

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ATTACHMENT F

FREQUENTLY ASKED QUESTIONS (FAQ) INFORMATION

Frequently Asked Questions (FAQ) Information

What is the purpose of this study?

The Centers for Medicare & Medicaid Services (CMS), the agency that oversees Medicare, wishes to understand why physician practices decided to participate, or not, in this program; physicians' satisfaction with the program; the program's impacts on Medicare costs and utilization; and impacts of the program on Medicare beneficiaries. This survey of CAP-participating and non-participating physicians is important because it is the only way CMS can understand why practices decided to participate and physicians' satisfaction with the program.

Will I be paid?

Yes. We have enclosed a $25 in our first mailing. It is yours to keep even if you decide not to complete the survey! However, we hope you will be willing to help the CMS monitor this program and take physicians' views into account when evaluating potential changes to the program.

How long will it take?

For CAP-participating physicians, it will take no longer than 15 minutes to read this information and complete the survey.

For physicians who have not elected to participate in the CAP program, it will take no longer than 8 minutes.

How can I complete this survey about the CAP program?

There are three convenient ways to complete the survey:

1) Complete the **enclosed survey** and return in the return envelope or by fax to XXX-XXX-XXXX.
2) Go to www.XXXXX.gov to complete an **on-line survey**
3) Call us toll-free at 1-XXX-XXX-XXXX to complete the survey **by telephone**

Who is conducting this study?

The Centers for Medicare & Medicaid Services (CMS), the agency that oversees Medicare, including the CAP program, is conducting this study. CMS has contracted with RTI International, a not-for-profit research organization, to evaluate the CAP program's effects on Medicare costs and utilization, physician satisfaction, and beneficiaries' satisfaction. This survey is the only way for CMS to understand why physicians participated and their satisfaction with the program.

What is RTI?

RTI International is an independent, not-for-profit research organization headquartered in North Carolina. For more than 40 years, RTI has dedicated to conducting research that performs various types of social science research and program evaluation for government clients. For more information, see http://www.rti.org. CMS has asked RTI International to administer this survey about the CAP program.

ATTACHMENT G

CAP PARTICIPATING PHYSICIAN SURVEY

This questionnaire has been sent to you because this practice has elected to participate in the Medicare Part B Drug Competitive Acquisition Program (CAP).

When answering each question, please think about *your* experiences at this practice. Feel free to consult with colleagues if necessary. Throughout this survey, the term "Medicare patients" refers to the elderly and qualified disabled persons who are covered under Medicare but may also have other health insurance coverage.

Please answer all questions by marking an "X" in the box to the left of your answer, like this:

- ☒ Yes
- ☐ No

Participation and Overall Satisfaction

1. How would you rate your overall satisfaction with the CAP (information and service provided by CMS and the CAP vendor BioScrip) since you elected to participate? *(Choose One)*

- ☐1 Very satisfied
- ☐2 Somewhat satisfied
- ☐3 Not very satisfied
- ☐4 Not at all satisfied

2. Has your overall satisfaction with acquiring Medicare Part B drugs and biologicals for Medicare patients *changed* since you elected to participate in the CAP? *(Choose One)*

- ☐1 No, it has not changed while I have participated in the CAP.
- ☐2 Yes, it has changed. I have become ***more*** satisfied.
- ☐3 Yes, it has changed. I have become ***less*** satisfied.

3. How would you rate your overall satisfaction with the payment system in place *before* you elected to participate in the CAP (the standard "buying and billing" or ASP method for Medicare Part B drugs)? *(Choose One)*

- ☐1 Very satisfied
- ☐2 Somewhat satisfied
- ☐3 Not very satisfied
- ☐4 Not at all satisfied

Reasons for Electing to Participate in the CAP

4. What was the *single* most important factor that influenced your practice's decision to participate in the CAP? *(Choose One)*

☐1 It was less costly to obtain Medicare Part B drugs under the CAP

☐2 There was no burden of "acquiring and billing" under the CAP

☐3 I/we often administer at least one of the drugs available under the CAP

☐4 I/we were already acquiring Medicare Part B drugs from BioScrip

☐5 *Other reason (please specify):*

5. Prior to the CAP election deadline, how would you rate your satisfaction with the information available to you about the CAP election process (who can elect, which forms to fill out, etc.)? *(Choose One)*

☐1 Very satisfied

☐2 Somewhat satisfied

☐3 Not very satisfied

☐4 Not at all satisfied

Overall Satisfaction with the CAP and the CAP Vendor, BioScrip

6. Overall, how would you rate your satisfaction with BioScrip, the single CAP vendor? *(Choose One)*

☐1 Very satisfied

☐2 Somewhat satisfied

☐3 Not very satisfied

☐4 Not at all satisfied

7. In general, how would you rate the following experiences with the CAP and the CAP vendor, BioScrip?

Experiences		How satisfied are you? *(Mark one answer in each row)*			
		Very satisfied	Somewhat satisfied	Not very satisfied	Not at all satisfied
a.	CAP drug ordering process as a whole?	☐	☐	☐	☐
b.	Information provided to you about the CAP drug ordering process?	☐	☐	☐	☐
c.	Selection of specific CAP drugs (manufacturer and dosage) available to order?	☐	☐	☐	☐
d.	Quality of the CAP drugs you have received?	☐	☐	☐	☐
e.	Timeliness of delivery for CAP drugs you obtain through BioScrip?	☐	☐	☐	☐
f.	Materials provided to you about the co-payment billing process (for patients)?	☐	☐	☐	☐

8. How would you rate the administrative burden of participating in the CAP (submitting orders, billing using required modifiers, etc.), *relative to that required for buying and billing Part B drugs under the ASP system*? *(Choose One)*

☐1 Much less burdensome

☐2 Somewhat less burdensome

☐3 Equally burdensome

☐4 Somewhat more burdensome

☐5 Much more burdensome

9. Have you encountered any problems with the "Emergency Drug Administration" process?

Emergency Drug Administration is a process whereby in emergency situations when waiting for a CAP order to be filled would be infeasible, you administer a drug from your practice's own stock, and then place an order with BioScrip to refill your stock?
(Choose One)

☐1 Yes

☐2 No → **(SKIP TO QUESTION 11 ON PAGE 4)**

☐3 Not Applicable: I have not needed to use this process → **(SKIP TO QUESTION 11)**

10. What problems have you encountered with the "Emergency Drug Administration" process? *(Choose All That Apply)*

☐1 BioScrip did not replace the emergency drug in a timely manner

☐2 I experienced payment denials from my local carrier/supplier

☐3 BioScip did not replace drugs of same quality that I used from my own inventory

☐4 *Other problem* (please specify):

11. Have you encountered any problems with the "Furnish as Written" (FAW) process?

Furnish as Written (FAW) is a process whereby due to a patient's medical necessity, you administer a formulation, brand, or NDC of a drug that is different from what is available from BioScrip? *(Choose One)*

☐1 Yes

☐2 No → **(SKIP TO QUESTION 13)**

☐3 Not Applicable: I have not needed to use this process → **(SKIP TO QUESTION 13)**

12. What problems have you encountered with the "Furnish as Written" (FAW) process? *(Choose All That Apply)*

☐1 My acquisition cost exceeded my Medicare payment

☐2 I experienced payment denials from my local carrier/supplier

☐3 *Other problem (please specify):*

13. How often have you experienced wastage (unused portions) of at least one-quarter of a package *for your CAP drug orders*? Your best estimate is fine. *(Choose One)*

☐1 Seldom—at most 1 out of every 10 drug administrations

☐2 Sometimes—1 or 2 out of every 10 drug administrations

☐3 Often—between 3 and 5 out of every 10 drug administrations

☐4 Very often—more than 5 out of every 10 drug administrations

14. Has BioScrip always filled the orders you have placed with them? *(Choose One)*

☐1 Yes → **(SKIP TO QUESTION 16)**

☐2 No

15. What reason(s) did BioScrip give for not filling some of your orders?
(Choose All That Apply)

☐1 They stated that the drug I ordered was not in stock

☐2 They stated that the beneficiary I ordered for has not made co-payments for previous CAP orders

☐3 They gave some other reason (*please specify*):

☐4 They did not give a reason for not filling an order

Reactions of Your Medicare Patients to BioScrip, the CAP Vendor

16. Have any of your Medicare patients reported problems to you related to co-payment billing by BioScrip? *(Choose One)*

☐1 Yes

☐2 No → **(SKIP TO QUESTION 18 ON PAGE 6)**

17. What problem(s) have your Medicare patients reported related to co-payment billing by the CAP vendor BioScrip? *(Choose All That Apply)*

☐1 Inaccurate co-payment amounts

☐2 Confusing billing statements

☐3 Requests for co-payments for products the patient cannot identify receiving

☐4 Unsatisfactory patient-focused customer service by BioScrip

☐5 Overly aggressive co-payment collection

☐6 Other problem (*please specify*):

18. Have your Medicare patients reported any greater inconveniences since your practice began participating in CAP? *(Choose One)*

☐1 Yes

☐2 No → **(SKIP TO QUESTION 20)**

19. What inconvenience(s) has/have for your Medicare patients reported? *(Choose One)*

☐1 Drugs were not received for the scheduled patient appointment

☐2 Patients had to wait for treatment because originally requested products were not available

☐3 Patients were referred to other providers because I did not have emergent need drugs on hand

☐4 Other inconvenience (*please specify*):

This final group of questions will provide researchers with some information about you and your practice

Additional Information

20. What proportion of your patients who receive physician-administered drugs are Medicare beneficiaries? Your best estimate is fine. *(Choose One)*

☐1 Less than 25 percent

☐2 Between 25 and 50 percent

☐3 Between 51 and 75 percent

☐4 More than 75 percent

☐5 Don't Know

21. How long have you been a practicing physician? *(Choose One)*

☐1 More than 20 years

☐2 Between 11 and 20 years

☐3 Between 5 and 10 years

☐4 Fewer than 5 years

22. How many physicians are in this practice? *(Choose One)*

☐1 I am a solo practitioner

☐2 2 to 4

☐3 5 to 9

☐4 10 to 99

☐5 100 or more

23. Is this practice single or multi-specialty? *(Choose One)*

☐1 Single specialty

☐2 Multi-specialty

24. Who owns the practice? *(Choose One)*

☐1 Physician or physician group

☐2 HMO

☐3 Community Health Center

☐4 Medical/Academic health center

□5 Other type (*please specify*):

25. How would you characterize the type of drug *you* most frequently administer in this practice for all patients? *(Choose One)*

☐1 Oncology-related

☐2 Rheumatological

☐3 Ophthalmological

☐4 Hematopoietic (not chemotherapy-related)

☐5 Parenteral nutrition

☐6 Cardiovascular

☐7 Anti-infectives (e.g., antibiotics, antivirals, antifungals)

☐8 Parenteral pain medication

☐9 Influenza or pneumococcal pneumonia vaccine

☐10 Other vaccine

☐11 Other → *Please specify*:

Thank you very much for your participation!

Please return completed questionnaire in the business-reply envelope to:

RTI International
ATTENTION
ADDRESS LINE 1
ADDRESS LINE 2
CITY, STATE XXXXX

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-XXXX**. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850

ATTACHMENT H

CAP NON-PARTICIPATING PHYSICIAN SURVEY

This questionnaire has been sent to you because this practice has elected not to participate in the Medicare Part B Drug Competitive Acquisition Program (CAP). When answering each question, please think about *your* experiences at this practice. Feel free to consult with colleagues if necessary.

Please answer all questions by marking an "X" in the box to the left of your answer, like this:

- ☒ Yes
- ☐ No

1. What was the *single* most important factor that influenced your practice's decision not to participate in the CAP? *(Choose One)*

- ☐1 It was more costly to obtain Medicare Part B drugs under the CAP
- ☐2 I/we preferred to use our existing carrier/supplier(s) for Medicare Part B drugs
- ☐3 I was/we were concerned about the CAP vendor's timeliness and accuracy in filling orders
- ☐4 I/we rarely administer any of the drugs available under the CAP
- ☐5 I was/we were concerned about the availability of specific formulations or brands of drugs, even though they are available under the CAP
- ☐6 *Other reason (please specify):*

2. How would you rate your overall satisfaction with the standard "buying and billing" method for Medicare Part B drugs (ASP+6% payments)? *(Choose One)*

- ☐1 Very satisfied
- ☐2 Somewhat satisfied
- ☐3 Not very satisfied
- ☐4 Not at all satisfied

3. In general, how would you rate the following experiences with your primary Medicare Part B drug supplier?

Experiences		How satisfied are you? *(Mark one answer in each row)*			
		Very satisfied	Somewhat satisfied	Not very satisfied	Not at all satisfied
a.	Drug ordering process as a whole?	☐	☐	☐	☐
b.	Selection of specific drugs (manufacturer and dosage) available to order?	☐	☐	☐	☐
c.	Quality of the drugs you have received?	☐	☐	☐	☐
d.	Timeliness of delivery for drugs you obtain?	☐	☐	☐	☐

4. What proportion of your patients who receive physician-administered drugs are Medicare beneficiaries? Your best estimate is fine. *(Choose One)*

☐1 Less than 25 percent

☐2 Between 25 and 50 percent

☐3 Between 51 and 75 percent

☐4 More than 75 percent

☐5 Don't Know

5. How long have you been a practicing physician? *(Choose One)*

☐1 More than 20 years

☐2 Between 11 and 20 years

☐3 Between 5 and 10 years

☐4 Fewer than 5 years

6. How many physicians are in this practice? *(Choose One)*

☐1 I am a solo practitioner

☐2 2 to 4

☐3 5 to 9

☐4 10 to 99

☐5 100 or more

7. Is this practice single or multi-specialty? *(Choose One)*

☐1 Single specialty

☐2 Multi-specialty

8. Who owns the practice? *(Choose One)*

☐1 Physician or physician group

☐2 HMO

☐3 Community Health Center

☐4 Medical/Academic health center

☐5 Other type (*please specify*):

9. How would you characterize the type of drug *you* most frequently administer in this practice for all patients? *(Choose One)*

☐1 Oncology-related

☐2 Rheumatological

☐3 Ophthalmological

☐4 Hematopoietic (not chemotherapy-related)

☐5 Parenteral nutrition

☐6 Cardiovascular

☐7 Anti-infectives (e.g., antibiotics, antivirals, antifungals)

☐8 Parenteral pain medication

☐9 Influenza or pneumococcal pneumonia vaccine

☐10 Other vaccine

☐11 Other → *Please specify*:

Thank you very much for your participation!

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