Greater New York Hospital Association
555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

May
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The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of the more than 150 voluntary and public hospitals represented by the Greater New York Hospital Association (GNYHA), I appreciate this opportunity to comment on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (MSSP) (Statement). GNYHA and its members are grateful for the collaboration taking place between the Department of Justice, Antitrust Division (DOJ) and the Federal Trade Commission (FTC) (collectively "the Agencies"), and for the Agencies' understanding of the significance of the proposed ACO regulations. As the Statement is a critical first step in potential implementation of ACOs, we respectfully request a number of revisions so that our members may utilize the Agencies' guidance as productively as possible.

Our major concerns involve the following points:

- As written, the Statement does not provide adequate guidance or assurances to promote participation in the MSSP as an ACO and may inadvertently create barriers to ACO development. This is an unmatched opportunity for the Agencies to promote ACOs and

clinically integrated health care organizations in general, and we respectfully encourage you to fulfill that opportunity.

- The methodology for determining the would-be ACO participants' share of the Primary Service Area (PSA) is ambiguous and costly. Moreover, it is based on a technique not generally used by geographic information system (GIS) professionals, especially in relation to the contiguity requirement, which we respectfully question. Reliance on the methodology as currently proposed would require a significant investment of hospitals' resources to perform an antitrust assessment even before making an application to the MSSP. Though antitrust law is always an appropriate concern for health care providers, the methodology as set forth in the Statement would restrict rather than promote entry in the ACO arena due to the laborious and uncertain PSA share calculation process.

- The resulting "mandatory review" process is likewise burdensome and seemingly overly-inclusive. It also inverts the Agencies' longtime policies and practices, placing the burden of the antitrust analysis on the would-be ACO participants and transforming the Agencies into regulators. We question if this is the best use of resources on either side.

- There are a number of aspects of the Statement that remain unclear. Specifically, we seek clarity on the implication of the March 23, 2010 cut-off date and the meaning of "non-exclusive" as a requirement for participating hospitals so that an ACO may fall into the so-called Safety Zone. These and other areas could benefit from a more thorough explanation.

Background: GNYHA and Its Membership

GNYHA is a trade association representing more than 150 not-for-profit hospitals, both voluntary and public, in the New York City metropolitan area, throughout New York State, and in New Jersey, Pennsylvania, Connecticut, and Rhode Island.

GNYHA and its members have long been focused on increasing efficiencies to improve the provision of care, and our members have experience in sharing knowledge and operational best practices while remaining active competitors. GNYHA provides a range of member services, including a number of quality collaboratives in which participating hospitals work together to improve an identified quality of care concern, implement operational changes, and track resulting outcomes data. We also lead a vibrant Compliance Workgroup and active Legal Affairs Committee, which convene to review and discuss legal developments, compliance-related requirements, and corresponding operational best practices. In each instance, we firmly believe that our activities lead to better, more efficient, less costly patient care.

Though GNYHA does not act as legal counsel to our members, we provide significant legal education and technical support, ensuring that they are well-versed in their statutory and regulatory obligations on issues ranging from fraud to tax-exemption to antitrust concerns. The ACO proposals, including the Statement, are of great concern to GNYHA members' attorneys and compliance professionals, and our comments are provided on their behalf. We

hope you will accept them in the constructive spirit with which they are rendered, as it is in all of our best interests to create an ACO system that can work successfully.

Antitrust Barriers to ACO Formation

Broadly speaking, we respectfully question the extent to which the Statement may be relied upon for ACO development and operation. Like hospitals around the country, GNYHA and its members are committed to antitrust compliance, and we are in no way asking the Agencies to disregard appropriate antitrust controls where needed. Nonetheless, we remain worried that the Statement as proposed does not go far enough in easing the antitrust path so that hospitals and other providers can commit to ACO development, and clinical integration in general, with minimal risk.

The promotion of ACOs has been established as a comprehensive Federal policy priority, and hospitals and other providers are being asked to embrace an enormous change in system formation and health care delivery. To do so requires a corresponding evolution in governmental analysis and enforcement in a range of areas, including antitrust. Quite simply, our hospitals cannot do this alone. They need the clear guidance and commitment of the Agencies and other oversight bodies to effectuate this new process. While we appreciate the evident thought, work and care that have gone into the development of the Statement and the principles it represents, we respectfully seek additional guidance and clearance to facilitate ACO development and operations more fully.

Hospitals seek clear guidance on rule-of-reason review for ACOs and clinically integrated organizations generally.

To that end, we appreciate the Statement's clarification that Medicare ACOs meeting certain standards would be analyzed under a rule-of-reason review. This is an important assurance, as is the accompanying acknowledgment that the ACO integration criteria are sufficiently rigorous so that joint negotiations with commercial payers will be considered subordinate and reasonably related to the ACO's primary purpose. Again, we are grateful for the Agencies' care and thought on these issues.

Yet we respectfully seek more information on this point. It would be especially helpful to have guidance on how such an analysis would be applied. This information would assist hospitals and other providers as they form and operate ACOS and other clinically integrated organizations.

Though we recognize that the Statement is intended to establish a screen rather than provide a script for a full antitrust review, our members would be better served by more information on the actual components of a potential rule-of-reason analysis as they think through the implications of forming new organizations. Moreover, such a framework would be useful to hospitals and other providers as they contemplate clinically integrated organizations in general. This is a unique opportunity for the development of guidance on this critical point, and we request that you take this step.

We encourage the Agencies to reconsider the PSA methodology.

Notably, the Statement is built on the somewhat novel concept (in antitrust analysis, at least) of participant share of PSA. The calculation of this number requires data not yet made public by Medicare as well as a mapping of so-called PSAs that differs from geographic boundaries typically used for an antitrust analysis.

From the outset, we question the use of ZIP codes as the building block for PSAs. A ZIP code is a geographically linear route created for the purpose of mail delivery. Though legitimate and useful for that function, it does not officially delineate any geographic region. [1] It is thus imperfect, technically and practically, to attempt to define an area based on the use of contiguous ZIP codes. We note that New York State attempted to use ZIP codes similarly in establishing State financial assistance requirements within the last five years and was ultimately required to use a different building block-—in that case, counties—as many of the limitations of ZIP codes came to light. Furthermore, the determination of the contiguity of the ZIP Codes is not a trivial task. In fact, sometimes two ZIP Codes with large patient populations will not be contiguous simply because they are divided by an industrial/commercial development which has its own ZIP code.

One possible remedy to the problem with ZIP Codes is to remove the contiguity requirement, instead defining the PSA as "the *collection of* ZIP Codes from which the provider draws 75% of its patients" will make the definition technically more meaningful, and computationally less burdensome.

Beyond the reliance on ZIP codes to define a PSA, the Statement would then ask would-be applicants to calculate shares for each common service to be provided by *each* participating hospital and doctor (or group of doctors) within each provider's PSA. This is an expensive and labor-intensive process, particularly given the limitations of available data for non-Medicare services. While some have estimated this work will cost around $15,000-$20,000 per applicant, our preliminary discussions suggest this number could be much higher, considering the requirement that some providers will be required to rely on all-payer databases available in their states. This presents an enormous financial burden to health care providers that are already financially vulnerable. Agency staff members have indicated that the Statements are intended to establish a "quick screen for those ACOs that would not be a problem," but we do not agree that this is the result achieved.

Further, we worry about any fraud implications should hospitals undertake the PSA analysis on behalf of physicians. As others in the industry have noted, the physician self-referral or "Stark" law requires that compensation for health care providers be fixed in advance and paid only for hours worked. The Stark law could potentially be implicated if a hospital compensates physicians by organizing and paying for the costly analysis required to determine physician PSA

[1] Several private companies do provide geographic areas that approximate these linear delivery routes. However, because there is no single, official delineation, different companies provide differing definitions of these areas. This of course will make the contiguity decision ambiguous. Furthermore, the definitions of the ZIP Codes are updated every quarter which may adversely impact the integrity of the analyses. For your convenience, we have attached an example of how approximations of ZIP codes can result in differing geographic areas.

shares. There is no indication in the notice issued by CMS and the Office of Inspector General on waivers in connection with the Medicare ACO program or that a waiver for such activities and expenses is being considered, but it is hard to imagine that hospitals will not need to assume this responsibility for participating physicians. We respectfully request that the Agencies address this potential problem.

The mandatory 90-day review is overly broad and resource intensive.

These potential risks and expenses grow when one considers the likelihood of mandatory review under the proposed Statement. That is, any prospective Medicare ACO applicant with 50% or more of a PSA share for any service or specialty will need to undergo mandatory antitrust review—even if the high share is for a non-Medicare service, such as pediatrics, and even if the applicant's PSA share is well below 50% for the vast majority of services provided. We worry that this sets too low and firm a trip wire and suggest a higher cut-off standard and/or a different method of analysis for assessing a comprehensive view of the applicant's role in the market.

Moreover, we note that the Agencies' concern over providers serving larger number of patients may not comport with CMS' stated view that "the more patients an ACO sees for which it is eligible to receive performance-based incentives, such as shared savings, the more likely it is that the ACO will adopt substantial behavior changes conducive to improved quality and cost savings." Presumably an ACO needs a large patient population to work effectively, yet the Agencies' screen is set to question such an ACO automatically.

The determination that an applicant must undergo a mandatory review is a significant one. The process will scrutinize the entire Medicare ACO applicant and its operations, regardless of how the provider fell into mandatory review. Again, this would create an enormous operational and financial burden for health care providers. The Statement would require the submission of an extensive set of documents and data, some of which may not yet be fully developed in light of the infancy of many ACOs. The preparation and submission of these materials will again require the engagement of outside counsel and additional consultants at considerable cost to the would-be ACO applicant. We respectfully question whether the information requested, much of which is related to the commercial insurance market, is the proper litmus test for potential entry into the Medicare ACO program so closely regulated by the Federal government, particularly in a market where Medicare and Medicaid have the larger shares, as noted above.

The 90-day review process may not be efficient.

In terms of process, we question whether the system proposed in the Statement is as efficient as it could be. Though we recognize the import placed on antitrust in the broader proposed ACO regulations, we question whether a full, preliminary 90-day review is always necessary. Some speakers at the recent FTC Public Workshop on Antitrust and ACOs suggested a more structured process within the 90-day window and more ongoing communication between the applicant and Agency staff throughout the process. As discussed, such a system could potentially include some sort of "early termination" by which the Agency staff determines that a full 90-day review is not necessary. This is not dissimilar to existing models of antitrust review and would save time and resources for both sides, particularly given the inevitable evolution that will occur under this new system of review.

Others have proposed a simultaneous review by the Agencies and CMS (of the broader ACO application), which again would presumably allow for communication and exchange throughout the process. We would support such notions, allowing for greater flexibility and fewer mandated submissions as a means of reducing the burden of even making an ACO application.

The mandatory review process changes the role of the Agencies.

As we have noted in these comments, aspects of the Statement create significant burdens and expenses for would-be applicants. Ultimately, this is because the proposals in the Statement shift the bulk of a standard antitrust review from the Agencies—to be conducted in the case of an apparent antitrust violation—to the entities seeking to participate in the ACO. Going a step further, this change is premised on the fact that the Agencies in this instance are acting as preliminary regulators, which is not their typical role. Applicants are being asked to quantify and, to some extent, justify potential behavior without any indication of potential illegality. As mentioned, this shift is not without meaningful costs, and we are concerned that this fundamental change may ultimately deter applicants from seeking participation in the MSSP. This would be regrettable.

ADDITIONAL REQUESTS FOR CLARIFICATION

In addition to these basic concerns, we have additional questions about the Statement. It would be extremely helpful to have clarification from the Agencies on these issues.

We seek additional information on the issue of "non-exclusivity."

We have fundamental questions about the requirement of non-exclusivity. Among other providers, hospitals are required to be non-exclusive to an applying ACO for inclusion in the Safety Zone. We are not certain what this means: if a hospital could legally enter into more than one ACO but elects not to for practical reasons, is this hospital acting in a prohibitively exclusive manner? We are not sure exactly what being "non-exclusive" entails.

In addition, we respectfully question whether the requirement makes sense for developing ACOs. Though our members have a healthy range of ideas and objectives related to potential ACO formation, some would plan to head up or be significantly involved in the development of an ACO. One must naturally wonder why such a hospital would then wish to join a competing ACO at the same time. On a simpler level, a hospital may well decide to limit its ACO involvement out of the sheer commitment of resources and culture change that participation in an ACO will require. Participation in one ACO may simply be as much as that particular hospital can manage, and that decision should not be viewed suspiciously.

We would appreciate more developed guidance and more situation-appropriate latitude from the Agencies as you consider this issue.

We question the need for and impact of the March 23, 2010, cut-off date.

We seek clarification on the March 23, 2010, cut-off dated cited in the proposed Statement. Evidently the Statement only applies to collaborations formed after that date, and we respectfully question the need for and the implications of such a firm threshold. There are existing, effective

health care collaborations formed prior to that date that are functioning successfully and legally, but the Statement does not anticipate how such an organization is to be treated. As an example, existing IPAs may already be serving Medicare Advantage, and thus may already have the skills, attitude, and demonstrated success that CMS seeks. There is no reason to preclude such experienced, provider-oriented organizations from the MSSP by virtue of the statutory start date.

If the Agencies are indicating that such entities do not require any antitrust review, we would ask for a direct statement to that effect. In so doing, though, we ask the Agencies to address how that decision interacts with the larger CMS application process and what this implies for such an entity's future actions.

Overall, we urge the Agencies to ensure that appropriate antitrust protections and entry into the MSSP are available to collaborations formed before March 23, 2010.

CONCLUSION

Once again, we thank the Agencies for your commitment to collaboration with each other and the provider community. We share your interest in both antitrust compliance and the appropriate development of ACOs, and we are confident that we can resolve any concerns collectively. Please do not hesitate to contact Deborah Brown (brown@gnyha.org or 212.258.5314) with any questions about this letter. We appreciate your consideration.

Sincerely,

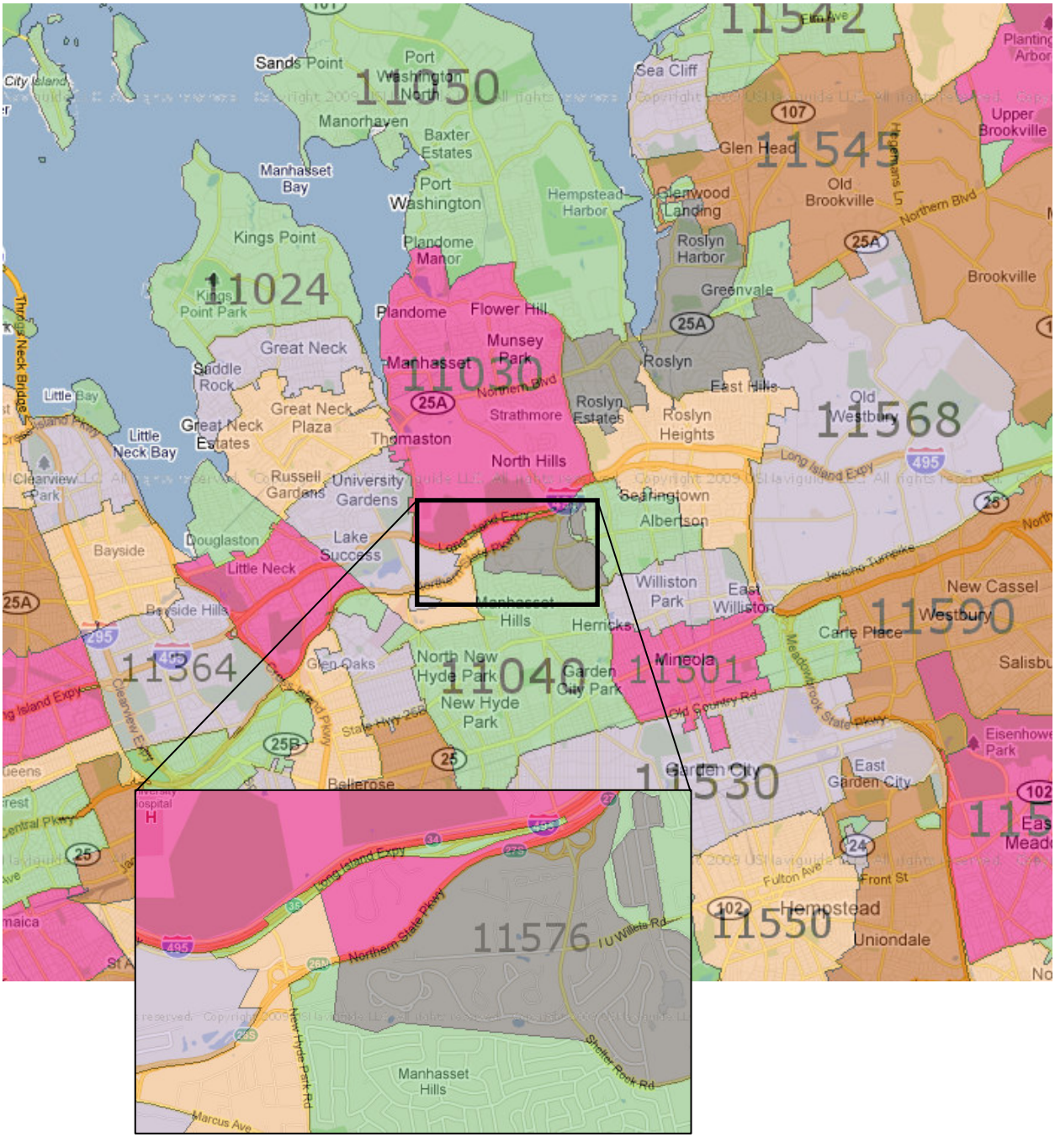
Kenneth E. Raske
President

GNYHA Comments: Attachment

The following graphs show two sets of delineations of the same ZIP Codes from two different data sources. As can be seen, the results are quite different for some ZIP Codes. Furthermore, the graphs show how two ZIP Codes with large patient populations might not be contiguous simply because they are divided by an industrial/commercial development with its own ZIP code.

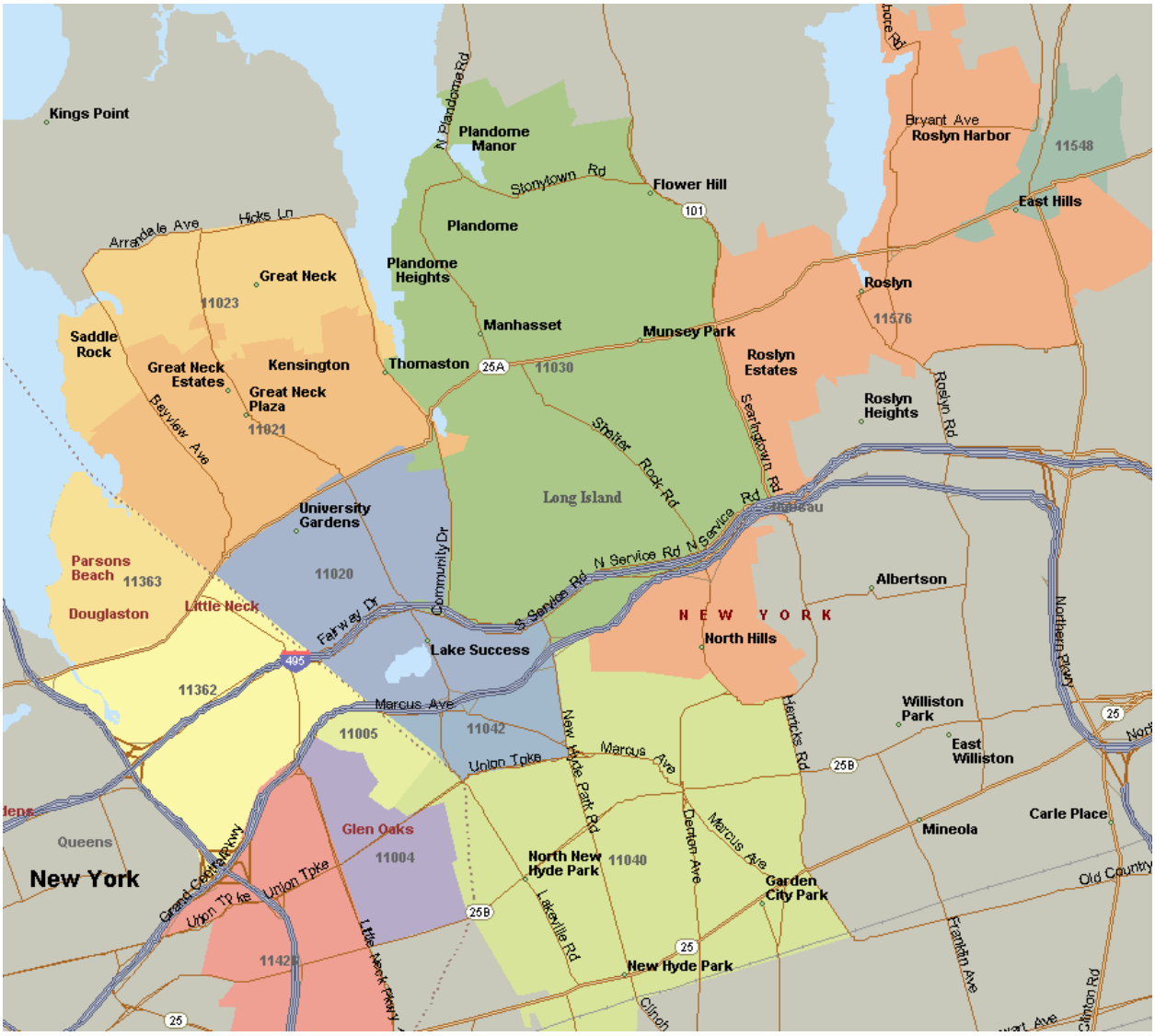
In the first graph, you can observe that part of the ZIP code 11040 (shown in green, along the Long Island Expressway) is completely detached from the larger area. We have provided a close-up view of this example for your convenience. The second graph shows the same area delineated differently, illustrating our concern with the proposed use of contiguous ZIP codes.

GRAPH 1



Source: http://maps.huge.info/zip.htm

GRAPH 2



Source: Microsoft MapPoint 2010