# SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") (collectively, the "United States"), and Advanced Care Scripts, Inc. ("ACS") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

# **RECITALS**

- A. When a patient obtains a prescription drug covered by Medicare, the patient may be required to make a payment, which may take the form of a "copayment," "coinsurance," or "deductible" (collectively "co-pays"). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration which includes money or any other item of value (such as a co-pay) to induce Medicare beneficiaries to purchase, or their physicians to prescribe, the companies' drugs that are reimbursed by Medicare.
- B. ACS is a Florida corporation with its principal office located in Orlando, Florida.

  ACS operates a specialty pharmacy and also has provided services to pharmaceutical companies.
- C. The United States contends that ACS: received payments from Teva Neuroscience, Inc. ("Teva"), which sells Copaxone; arranged for third parties to cover Medicare patients' copays for Copaxone; and then submitted, or caused to be submitted, claims for payment for Copaxone to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III ("Medicare").
- D. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against ACS for engaging in the conduct below (hereinafter referred to as the "Covered

4. When the co-pay funds operated by the foundations lacked funding and were not accepting new applications for Medicare co-pay coverage, ACS provided regular updates to Teva on the number of Medicare Part D patients serviced by ACS who had prescriptions for Copaxone, met the criteria for foundation co-pay coverage, and were awaiting foundation co-pay coverage. At least one ACS employee understood that Teva would use the number of waiting Copaxone patients to help determine the amount of its next payment to CDF or TAF. Teva sometimes provided ACS with advance notice of its payments to CDF or TAF. Once ACS learned that CDF or TAF had re-opened its co-pay fund, ACS promptly would send the foundation information, often in a "batch file," that consisted almost entirely of Copaxone patients' applications for Medicare co-pay coverage. Thereafter, ACS often received notice from the foundation that most or all of the applications submitted by ACS had been approved to receive co-pay funding. When a Copaxone patient's application was approved, ACS no longer included that patient in its reports to Teva on the number of Copaxone patients awaiting foundation co-pay coverage.

As a result of the foregoing conduct, the United States contends that ACS caused false claims to be submitted to Medicare.

ACS acknowledges the facts set forth in paragraphs D.1 through D.4, above.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

### TERMS AND CONDITIONS

1. ACS shall pay to the United States three million five hundred thousand dollars (\$3,500,000) (the "Settlement Amount") no later than ten days after the Effective Date of this Agreement (defined in Paragraph 20, below) by electronic funds transfer pursuant to written

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.
- 5. ACS waives and shall not assert any defenses ACS may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.
- 6. ACS fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that ACS has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.
- 7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by ACS, and ACS shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by ACS or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: ACS further agrees that, within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by ACS or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. ACS agrees that the United States, at a minimum, shall be entitled to recoup from ACS any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by ACS or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this

- 13. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.
- 14. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
- 15. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 16. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
- 17. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
  - 18. This Agreement is binding on ACS's successors, transferees, heirs, and assigns.
- 19. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 20. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

### THE UNITED STATES OF AMERICA

DATED:	BY:		
	Ī	GREGG SHAPIRO	
	,	ABRAHAM GEORGE	

# ADVANCED CARE SCRIPTS, INC.

DATED:

BY:

THOMAS S. MOFFATT

President

Advanced Care Scripts, Inc.

DATED:

BY:

S. CRAIG HOLDEN

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC Counsel for Advanced Care Scripts, Inc.