

# Opioid Prescribing Control Software(OPCS) (1 R43 DA018527-01)

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Developer's NAIC: 511210 Software Publisher

Science/Technology Fields: Pain, Opiates, Computer Science

Arena NAIC: 325411 Medicinal and Botanical Manufacturing

Library of Congress Subject Heading: RM121- Prescription Writing

Technology Type: Software information/control system

Supply Chain: Health/Processing Tools & Techniques

International Patent Classification: G06K Presentation of Data; Record Carriers; Handling Record  
Carriers

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# 1 Executive Summary

The following is a non-proprietary description of this technology.

<i>Non-Proprietary Description of Technology</i>
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OPCS is “the first office-based, computer-assisted learning tool for primary care physicians who treat chronic pain with long-term opioids.” <sup>1</sup>
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This technology seeks to systematize the primary physician’s approach to prescribing Class II narcotic drugs by use of an interactive computer-based platform. The physician will achieve:

- Greater specificity in prescribing the appropriate drugs for the type of pain presented
- Better control of functional outcomes for the patient
- Easier and more comprehensive transfer of relevant patient information
- Automatic interface with state and national drug control information sources to ensure the patient isn’t “doctor shopping” for multiple prescriptions
- Increased patient compliance and reduced patient drug abuse through use of written “Doctor-Patient” agreements; and
- Decreased liability for mis- or over-prescribing because of detailed and automatic patient records and reporting

What makes this technology a scientific/engineering innovation is:

<i>Non-Proprietary Description of the Key Innovation(s) Underlying the Technology</i>
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OPCS goes beyond existing models of physician education, combining an interactive education medium, a collaborative physician-patient relationship, and computerized tools for measuring functional outcomes. OPCS’s other notable innovations over prior art include:
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| <ul style="list-style-type: none"><li>• Integration of a screen for prescription-drug abuse into an interactive and dynamic software program</li><li>• Creation of specific data points and conclusions that support the physician’s clinical decisions and can be easily stored in, retrieved, and referenced within the patient’s medical record</li><li>• Enhanced patient education, resulting in genuinely informed consent</li><li>• Facilitation of functional goal-setting by the patient in collaboration with the prescribing physician</li><li>• Analysis of potential risk of addiction or abuse over time, based on assessment of functional outcomes over time</li><li>• Cost-containment and increased physician-time efficiency in office-based practice <sup>2</sup></li></ul> |
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— Redacted — wishes to license the OPCS software to manufacturers of Schedule II opioid drugs, after which such manufacturers would make the program available to physicians free or for a nominal fee. — Redacted — anticipates generating revenue from license fees paid by these pharmaceutical companies for permission to produce and distribute the OPCS software.

The end-user is defined as the person who ultimately uses the technology. Commercialization normally occurs when end-users buy the technology to utilize it in a practical application. In this case, — Redacted —’s strategy dictates that the end-users will use the technology, but not buy it; — Redacted —is targeting pharmaceutical companies, managed care companies and insurers to buy the technology, and then distribute it to the end-users.

<sup>1</sup> XX (President, — Redacted —), OPCS Commercialization Plan, p. 95.

<sup>2</sup> *Ibid*

*End-User(s)*

The end-users of this technology will be physicians [MDs]. The Bureau of Labor Statistics, which classifies physicians and surgeons together, describes them in the following manner: “Physicians and surgeons serve a fundamental role in our society and have an effect upon all our lives. They diagnose illnesses and prescribe and administer treatment for people suffering from injury or disease. Physicians examine patients, obtain medical histories, and order, perform, and interpret diagnostic tests. They counsel patients on diet, hygiene, and preventive healthcare. Physicians work in one or more of several specialties, including, but not limited to, anesthesiology, family and general medicine, general internal medicine, general pediatrics, obstetrics and gynecology, psychiatry, and surgery.”<sup>3</sup>

Internists and Family/General Practitioners (Primary Care Physicians or PCPs) are the prime prospects for the OPCS pain management software. Pain Management Specialists routinely deal with opioids for pain management and, therefore, need less support in choosing and using Opioids for pain management. They do, however, still need effective means of curtailing drug misuse and complying with increasingly stringent federal documentation and reporting requirements.<sup>4</sup> Family and general practitioners are often:

“the first point of contact for people seeking health care, acting as the traditional family doctor. They assess and treat a wide range of conditions, ailments, and injuries, from sinus and respiratory infections to broken bones and scrapes. Family and general practitioners typically have a patient base of regular, long-term visitors.”<sup>5</sup>

General practitioners are seeing increased incidence of conditions requiring pain medication with opioids; in addition to the documentation and reporting requirements, GPs are less familiar with the detailed pharmacology of opioids and will benefit from computerized assistance in choosing appropriate opioid compounds, dosages and regimens.<sup>6</sup>

An application is a potential use for a technology that is based on end-user needs and could provide a feasible market opportunity for the technology. The following table presents our choice for an initial market entry application.

*Recommended Application*

The recommended application of the OPCS software, as identified by — Redacted —, is a computer assisted learning tool for Primary Care physicians and Pain Management Specialist physicians, in private or group practices.

Since only certified physicians may prescribe opioid drugs, the end-user market for this technology is clearly focused on physicians. Two distinguishable physician specialties comprise the primary market: [1] Pain Management Specialists, and [2] General Practitioners [GPs].

It is also helpful to understand that potential purchasers of new technologies are divided into different classes according to their receptivity to the introduction of those technologies. For example, Early Adopters tend to quickly embrace relevant new technologies, while Traditionalists wait until a technology has established and proven itself before adopting it. Since Pain Management is a relatively new medical

<sup>3</sup> Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2004-05 Edition*, Physicians and Surgeons, on the Internet at <http://www.bls.gov/oco/ocos074.htm> (visited March 9, 2005).

<sup>4</sup> Dr. Aaron Gilson (Assistant Director, Pain & Policy Study Group, University of Wisconsin), 608-263-7662, in a telephone conversation with Norman Brown, March 10, 2005.

<sup>5</sup> BLS, *Occupational Outlook Handbook, 2004-05 Edition*, <http://www.bls.gov/oco/pdf/ocos074.pdf> (accessed March 23, 2005)

<sup>6</sup> Dr. Aaron Gilson (Assistant Director, Pain & Policy Study Group, University of Wisconsin), 608-263-7662, in a telephone conversation with Norman Brown, March 10, 2005.

specialization and is directly focused on pain management, most Pain Management Specialists are aware of the issues which the OPCS software addresses, and should be positively disposed to consider this technology; they would thus be the logical initial target.<sup>7</sup> Those contacted expressed a high willingness to consider the OPCS approach and, if the technology were to work well, to adopt it.

The key competitive advantages of the software, however, are principally oriented to the needs of the more traditional GPs. GPs see a much greater number of patients than Pain Management Specialists, but have a reduced awareness of specific opioid pharmacology.<sup>8</sup> They may also be less aware of governmental reporting requirements surrounding opioid prescription. Adoption by GPs is likely to be slower and more of a challenge.<sup>9</sup> Strategies that identify early-adopting GPs focus on continuing medical education activities, and emphasize ease of adoption are likely to be preferred for the GP market segment. Pain Management Specialists are likely to be early adopters of the new technology; accordingly, the first primary target-market of interest would be the early-adopting Pain Management Specialists and the secondary target-market would be GPs. This approach was endorsed by two of the experts contacted thus far.<sup>10</sup>

We also identified other potential applications for the technology.

<i>Other Applications Identified</i>	
<i>Application</i>	<i>Potential Competitive Advantages of Technology</i>
Non-opioid controlled drug prescribing	The basic competitive advantages of the OPCS software -- providing complex drug information, monitoring patient use, checking against state and federal databases for misuse, and facilitating reporting/record-keeping -- apply to other classes of controlled drugs. Only relatively minor additions of information and decision-trees would be needed for this application. The rest of the software's functionality would be virtually unchanged.  Federal attention and professional liability are currently strongest in the area of narcotic drugs. However, there are also a number of non-narcotic prescription drugs that are also considered controlled drugs; many sedatives, tranquilizers and stimulants are controlled substances. Ritalin, for instance is a Schedule II drug, like most opioids. Any drug that is deemed abusable is a controlled substance, and assigned to a schedule of I-V, depending on the abuse potential. Most benzodiazepan sedatives are schedule III. Governmental reporting and drug information advantages of OPCS will be equally relevant for these drugs, requiring careful monitoring of patients' use and treatment plans. <sup>11</sup>
Non-controlled drug prescribing	Federal attention and professional liability are currently strongest in the area of controlled drugs. However, there are also a number of non-narcotic prescription drugs that are subject to misuse. Examples are Cox-2 NSAIDS (such as Celebrrex and Vioxx), that aren't abuseable but require post-market pharmacovigilance and reporting for adverse outcomes. Though the governmental reporting and drug information advantages of OPCS may be less relevant, careful monitoring of patients' use of these drugs is also of concern to the medical profession and OPCS can serve a supporting role in these functions.
Chronic Disease	Chronic Disease Management, such as diabetes and hypertension, also involve

<sup>7</sup> Kathryn Padgett, Ph.D. (Executive Director, American Academy of Pain Management), 209-533-9744, in separate telephone conversations with Norman Brown, March 10, 2005.

<sup>8</sup> Jennifer Schneider, "Addiction and Chronic Pain", National Pain Foundation website, [http://www.painconnection.org/MyEducation/MyEducation\\_Addiction\\_and\\_Chronic\\_Pain.asp](http://www.painconnection.org/MyEducation/MyEducation_Addiction_and_Chronic_Pain.asp), (accessed Mar 10, 2005).

<sup>9</sup> Kathryn Padgett, Ph.D. (Executive Director, American Academy of Pain Management), 209-533-9744, in telephone conversations with Norman Brown, March 10, 2005.

<sup>10</sup> Dr. Aaron Gilson (Assistant Director, Pain & Policy Study Group, University of Wisconsin), 608-263-7662 and Kathryn Padgett, Ph.D. (Executive Director, American Academy of Pain Management), 209-533-9744, in separate telephone conversations with Norman Brown, March 10, 2005.

<sup>11</sup> XXX, in telephone conversation with Norm Brown April 1, 2005

Management	systematic tracking of biomarkers, patient activities, and functional outcomes over time. OPCS's functionality may well be adaptable to these chronic diseases as well as chronic pain. <sup>12</sup>
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The following material is available on this technology.

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<sup>12</sup> *Ibid.*